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Perspective

Need for a New Federal Approach for Responding to Chemical Exposure Caused by Community-Wide Contamination

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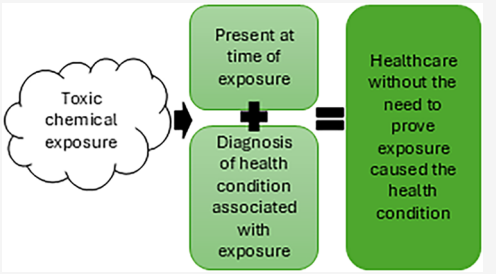
ABSTRACT: When communities are exposed to environmental chemicals, the federal government's response relies on scientific evidence to prove that adverse health conditions were caused by the particular chemical exposure. However, the lack of robust exposure information and a minimal understanding of cumulative effects means critical information required to prove causation is rarely available. As a result, the government often fails to adequately protect public health. We propose a response model based on presumptive association that would allow government to act in the absence of community-specific data linking cause and effect after community-wide chemical exposures. In this model, when a community is exposed to a chemical of concern, agencies would review scientific information about the health effects of exposure to that chemical. If the evidence indicates the chemical could cause a certain health condition, then the government would take action to benefit community members who were exposed and who have that condition. They would not have to prove that their health condition was caused by exposure to the chemical of concern. Adopting a presumptive association model for federal responses to chemical exposures would create a clear, fair, standardized, and timely approach that protects public health.



KEYWORDS: *presumptive association, public health, risk assessment, recommendations, environmental justice*

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INTRODUCTION

The Agency for Toxic Substances and Disease Registry (ATSDR)[1] and the US Environmental Protection Agency (EPA)[2] are the primary federal agencies responsible for responding to and investigating area-wide community exposures to toxic chemicals such as occurred in East Palestine Ohio where a train derailed leading to the intentional burning of a number of tanker cars containing toxic chemicals. This accident led to the release of a toxic cloud into the surrounding neighborhoods and farms in Ohio and Pennsylvania.[3] Immediately after the burn, people in East Palestine began reporting adverse health symptoms including headaches, nose bleeds, skin rashes, central nervous system symptoms, thyroid problems, and more. Despite these reports, EPA took no action to address the adverse health symptoms that the people were experiencing and continued to argue that there was no cause for concern. It is impossible to say with certainty what chemicals the people in East Palestine were exposed to, at what concentrations, and/or how long the exposure lasted. Because of the many unknowns about this exposure, the federal government did not take action to protect public health, and residents now face ongoing health consequences. It stands as an excellent example of how the federal government's response to area-wide chemical events going as far back as Love Canal in 1978, is inadequate to protect public health.

The frequent absence of a structured federal response and inadequate scientific methods for investigating health outcomes of exposure to toxic chemicals has resulted in continuing failure to protect communities. Health investigations typically take years to complete and often result in an uncoordinated multiagency investigation with little attention given to the specific health concerns of local residents.[4] Rarely do these investigations generate meaningful action to protect communities from ongoing and further harm. Meanwhile, communities like East Palestine are left with unanswered questions and many, often serious, health problems. The failure of the current response has an outsized impact on low-wealth populations and communities of color who are already disproportionately impacted by environmental hazards.

Examples of these failures span the entire country and a variety of exposure scenarios. For instance, natural gas drilling in Dimock, Pennsylvania in 2008 led to complaints of polluted drinking water. The state Department of Environmental Protection began testing, but with no relief, residents asked

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the EPA and ATSDR for help in 2011. ATSDR conducted a health consultation that determined the water to be unsuitable for drinking,[5] but this report was not released until 2016, with residents being exposed to chemicals for 8 intervening years.

In 2005, EPA sampling of soil and air near two industrial facilities in Birmingham, Alabama—a majority Black city with a poverty rate higher than the state average—found lead, arsenic, and benzo(a)pyrene. It took until 2014 for EPA to ask ATSDR to conduct a health consultation which was released in 2017 and concluded that past and ongoing exposure to arsenic in surface soil could harm residents' health,[6] 12 years after the initial evidence of contamination.

In 2000, in response to community concerns about emissions from a hazardous waste incinerator, EPA began air monitoring in East Liverpool, Ohio and found elevated levels of manganese and chromium.[7] In 2008 the Ohio EPA began enforcement actions and asked ATSDR to conduct a health consultation. This health consultation, released in 2010 provided recommendations for reducing community exposure to manganese,[8] 10 years after the initial acknowledgment of unsafe emissions.

In contrast to these delayed, uncoordinated responses, the federal government does have standardized, structured responses to many other public health threats including infectious disease,[9] foodborne illness,[10−13] and natural disasters,[14−19] key elements of which could be drawn on to design a new federal response model for investigating adverse health problems caused by community-wide exposures.

DISCUSSION

Current Government Response Uses a Risk Assessment and Causation Model. The government's current approach to assessing exposures to toxic chemicals relies on a risk assessment approach, where exposure data must be linked to health outcome data that "proves" that the adverse health effects reported or identified in a community are caused by a particular chemical exposure.[20] The scientific foundation of risk assessment is generally credited to the publication of the "Red Book" by the National Academy of Sciences (NAS) in 1983 which defined risk assessment as "the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials or situations".[21] But questions about the limitations and comprehensiveness of risk assessment quickly surfaced[22,23] and have continued to grow over the years.[24−27] Improvements in the risk assessment process have been offered by the National Research Council (NRC),[28] as the EPA and other government agencies continue to rely on this process to assess exposures to toxic chemicals and to evaluate area-wide exposure to multiple chemicals such as occurred in East Palestine.

While scientific accuracy is crucial, science and especially time-limited public health work will always have uncertainty associated with it, which makes proving timely causation nearly impossible to achieve. Additionally, communities are often exposed to multiple toxic chemicals, often simultaneously, but established health and environmental standards and guidelines are almost always based on exposure to a single chemical at a time. With little scientific information about cumulative exposure to multiple chemicals and limited tools to evaluate these exposures, there is even more uncertainty about potential adverse health effects.[29] Furthermore, there will always be some amount of fundamental uncertainty associated with physical, chemical, or biological measurements.[28] Concerns about the state of the scientific knowledge and understanding of the relationship between health outcomes and exposures in communities led to a recommendation by the 2011 ATSDR National Conversation on Public Health and Chemical Exposures that stated "CDC/ATSDR should initiate an independent review to evaluate the effectiveness and identify the limitations of scientific methods used by ATSDR and other health agencies to investigate the public health effects of community-wide exposures to toxic substances".[30] This and other related recommendations were never acted on by ATSDR and the government continues to rely on an outdated and limited approach that unrealistically relies on proving cause and effect in a community.

Government Response Should Follow a Presumptive Association Approach. The people in communities like East Palestine are facing nearly identical uncertainties about their health that the first responders and others exposed to toxic smoke resulting from the destruction of the World Trade Towers in New York City, and American soldiers exposed to emissions from burn pit smoke in Iraq and Afghanistan. In these situations, the federal government recognized that critical scientific information linking exposures and health outcomes was impossible to assess, missing, or incomplete (further described below). To address the needs of the victims and survivors, the government decided to use a presumptive association approach in evaluating the adverse health effects from which these groups of people were suffering.

We propose applying this same presumptive association approach to how the health problems in community-wide exposures such as occurred in East Palestine are evaluated. Rather than requiring proof of causation before action can be taken, the government would recognize that critical scientific information will almost always be missing or incomplete, and to protect public health it is necessary to make presumptions about chemical exposures leading to adverse health effects where data are appropriate. A presumptive association approach would give the government the ability to make decisions and act in the face of this uncertainty. When government fails to act in these scenarios, it can have secondary effects beyond just allowing communities to be exposed to toxic chemicals. The chronic stress of dealing with exposure can cause physiological effects[31,32] as well as feelings of institutional delegitimization if people believe their concerns are ignored.[32,33] A presumptive association approach could ameliorate these secondary effects in addition to addressing the immediate health impacts of exposure. A presumptive association approach would heavily rely on biological, chemical, medical, epidemiologic, and environmental evidence, and would build on the experience gained from its previous use in similar situations where people have been exposed to toxic chemicals and where critical information linking exposure and health outcomes was lacking.

Presumptive Association Methodology. In a presumptive association model, existing scientific information would be used to make two fundamental presumptions. The first presumption would address whether a person was exposed to toxic chemicals in an area-wide exposure situation. Once an area of concern has been identified, then any people present at the time and place of chemical exposure would be considered to have been exposed. Determining the exact geographic area of concern and how long people would have to be present there to be considered exposed will depend on the nature of the specific exposure and the properties of the chemicals involved. The second presumption addresses the health outcomes in a community. A group of scientific experts from government

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Environ. Sci. Technol. XXXX, XXX, XXX−XXX

and/or academic positions would be brought together to evaluate the scientific literature linking health outcomes related to the chemicals identified in the area of concern. These experts would perform a literature review of published information regarding the chemicals of concern found in a defined contaminated area.

This group of scientific experts could be convened, structured, and run in a variety of ways, and these rules may depend on the specifics of each case. For example, after the September 11th attacks, an act of Congress established a scientific and technical advisory committee made up of medical and environmental health specialists to review data and make recommendations for health conditions which had sufficient evidence linking them to exposure to toxic chemicals from the attacks. In the case of Agent Orange exposure to veterans of the Vietnam War, an expert committee of the Institute of Medicine was established to review the data and determine which health outcomes had sufficient evidence linking them to exposure to dioxin, the toxic ingredient in Agent Orange.

After analyzing the literature, the scientific expert group would classify the evidence as either "sufficient" to link exposure to the chemical(s) of concern to specific adverse health outcomes (at least as likely as not, which is often referred to as equipoise; or more so—above 50%), or "insufficient evidence at present" (or currently below equipoise). The expert group being convened for the purpose of evaluating a specific chemical and exposure would allow it to make targeted, focused determinations more quickly than largescale federal agencies currently do. Exposure to a chemical would be presumed to cause an adverse health effect if the evidence linking the chemical and the health effect is at least as likely as not or above. This equipoise concept for toxic exposures was first introduced in The Radiation-Exposed Veterans Compensation Act of 1988,[34] and as described by the Institute of Medicine, has since become the standard for using a presumptive association approach to service-connected health conditions of US veterans.[35]

Government Has Already Used a Presumptive Association Approach. The government has previously recognized that critical scientific information is missing or incomplete, making it necessary to make presumptions about exposure leading to adverse health outcomes. This was done when the government was considering adverse health effects suffered by veterans, active military, first responders, 9/11 victims and others exposed to toxic chemicals while serving their country or their government. Without this recognition, the government was stuck in a paradigm of relying on having to prove cause and effect before they could acknowledge that the illnesses these groups of people were suffering from were a result of exposure to toxic chemicals. By acknowledging and accepting these scientific limitations, in each of these cases the government was able to provide health care, treatment, compensation and other assistance needed due to the exposure to toxic chemicals. In communities where people have been exposed to toxic chemicals through no fault of their own, government could extend a similar application of the presumptive approach.

9/11 Survivors and First Responders. The September 11th attacks quickly resulted in nearly 3000 deaths and 6000 injuries. The destruction of the World Trade Center produced a toxic dust cloud composed of a mixture of particulate matter and chemical agents, some of which are known human carcinogens or linked to various respiratory illnesses.[36]

To help survivors and first responders involved in the attack, the September 11th Victim Compensation Fund (VCF) was established by the U.S. Department of Justice on September 22, 2001 to provide compensation for individuals who suffered physical injuries or took part in the cleanup efforts in the aftermath of the attacks. The James Zadroga 9/11 Health and Compensation Act of 2010 would later reactivate the VCF and lead to the creation of the CDC's World Trade Center Health Program (WTCHP) to provide additional medical benefits to victims.[37]

The WTCHP offers medical screening, monitoring, and treatment to 9/11 first responders and survivors with presumptive WTC-related health conditions. Importantly, people do not have to prove that their presence at the attack site caused their illness or injury in order to receive assistance. To establish these associated illnesses, the WTCHP's Scientific/Technical Advisory Committee (STAC) of medical and environmental health specialists completes extensive scientific literature reviews to identify health conditions associated with the chemicals of concern.

The main criteria for people to receive assistance through VCF are[38]

1. Proof certified by a program-affiliated physician of 9/11-related physical injury or condition listed as WTCHP's eligible presumptive illnesses.
2. Proof of presence at one of the attack sites or along debris removal routes during September 11, 2001 through May 30, 2002.
3. Proof that they belong to an eligible group (first responders and/or survivors).

Toxic Emissions from Burn Pits. In Middle Eastern combat zones following the September 11th attacks, it was common for the U.S. military to dispose of waste, chemicals, munitions, and other materials via open-air combustion commonly known as burn pits.[39] The smoke, fumes, particulate matter, dust, and fuel from these burn pits have since been linked to many types of cancer including brain, kidney, blood, skin, pancreatic, reproductive, and respiratory cancers.[40] Under the Honoring our Promise to Address Comprehensive Toxics (PACT) Act of 2022, more than 20 health conditions were presumed to be associated with burn pit exposure without regard to cause.[41] The Department of Veterans Affairs (VA) established a list of Middle Eastern countries in which they presume anyone who served was exposed to burn pits. To qualify for compensation and healthcare benefits from the VA, veterans must show proof of service in one of these areas after September 11th and present with one of the listed conditions. Veterans of the Vietnam and Gulf Wars also have access to health care and other compensation using presumptive association criteria under the PACT Act.[42]

Contaminated Drinking Water at Camp Lejeune, North Carolina. In 1982, two water treatment plants supplying drinking water to the Camp Lejeune Marine Corps base in Jacksonville, North Carolina were discovered to be contaminated with toxic chemicals including the carcinogens trichloroethylene (TCE), perchloroethylene (PCE), vinyl chloride, and benzene.[43] ATSDR conducted extensive modeling and determined that the drinking water was contaminated as far back as the early 1950s.[44] The contaminated supply wells were shut down by the end of 1985. Responding to the community's health concerns, Congress passed the Honoring American's Veterans and Caring for Camp Lejeune Families Act of 2012. Under this Act, the VA provides free healthcare to veterans and their families who show proof that they were stationed at or lived

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Environ. Sci. Technol. XXXX, XXX, XXX−XXX

on base between August 1, 1953 and December 31, 1987 and have a diagnosis of one of 15 qualifying presumptive conditions.[45] The presumptive conditions were based on a 2009 report by the NRC that reviewed the possible health effects of exposures to the chemicals in the Camp Lejeune drinking water.[46] A second VA program, established in 2017, provides service-related disability compensation to Marines and Navy personnel who show proof that they were stationed at Camp Lejeune between August 1, 1953 and December 31, 1987 and have one of 8 qualifying presumptive conditions. This list of presumptive conditions was based on an ATSDR review of the scientific evidence for associations between the chemicals and cancers and other chronic diseases.[43]

Implementation. Adopting a presumptive association approach to toxic chemical exposure in the environment would require reorienting the government's relationship to exposure events, science, healthcare, and communities. This would not come easily. Many difficult questions need to be addressed to implement this approach. These include questions about how to gain sufficient support to convince policy makers, government agencies, and responsible parties to adopt the presumptive association approach to address the many scientific uncertainties that exist in the fields of toxicology and public health. Almost all of the presumptive compensation programs discussed here needed federal legislation to make these programs a reality. These examples involved highly visible, sympathetic victims—which is not always true of widespread toxic chemical exposures—and still required years of public outcry and advocacy to spur federal action. It will require a variety of sustained strategies to promote public pressure and gain federal support for a presumptive association approach applied more broadly. There are also questions about the initiation of a government response, such as how to create a standardized, rapid response, and how federal agencies and the newly convened expert groups would play a role in literature reviews, assessments, and determinations regarding the health effects associated with chemicals of concern. The National Toxicology Program (NTP) and ATSDR would likely have important roles to play in this process. Furthermore, not all widespread chemical exposures have clear starting times or geographical boundaries, so making these determinations may not always be straightforward. Finally, there are healthcare questions such as how care can be offered to impacted residents quickly, what federal agencies would provide care, and how the government will pay for this care. As others have encouraged,[33,47] this research and action regarding widespread chemical exposures should include community participation.

There are existing federal programs that can offer insight into this process. For example, the Centers for Disease Control (CDC) Epidemic Intelligence Service (EIS) trains epidemiologists to rapidly investigate and respond to emerging public health threats, with the ability to conduct and publish health investigations within months. This program is focused on infectious and noninfectious disease outbreaks, unexplained illnesses or natural or man-made disasters.[48] ATSDR uses a similar response model called the Assessment of Chemical Exposures (ACE) program that deploys experts to investigate and respond to threats to human health after environmental emergencies. This program focuses on investigating environmental accidents and has been used after a gas pipeline explosion, a jet fuel leak, ammonia release, drinking water contamination caused by a petroleum leak, and a cargo train derailment.[49] In some instances, the EIS model and the ACE program have established registries that help to identify the population exposed during the accident. This experience could be valuable to a presumptive association model. One similarity that the ACE program shares with the proposed presumptive association model is that the ACE program uses ATSDR staff to gather information on the toxicity of the chemicals involved in the accident, much as the expert panel we propose would gather information on the chemicals people were exposed to in an area-wide community contamination. These staff experts could be valuable specialists who could help determine if there is sufficient scientific evidence to link exposure of a chemical of concern to a specific health condition. More broadly, the training and infrastructure of programs like EIS and ACE could also provide insight and support in setting up and implementing a presumptive association approach. One limitation of the ACE program is that it is intended to respond to chemical releases caused by an environmental accident, not to assess chronic contamination such as discussed in this presumptive association model. Another significant difference is that the ACE and EIS programs do not call for additional environmental sampling, which is a critical component of the presumptive association model. Although the ACE program does make some effort to include the community in its investigations, the proposed presumptive association model would ideally involve the community much more at the ground floor and throughout the process as an equal partner. Perhaps most importantly, the presumptive association model does not rely on having to prove cause and effect to take action in a community, as health studies typically do. For this reason, the presumptive model could greatly enhance and expand what these existing programs do because it would allow for clear decision-making and action from the government to protect public health in the absence of causal data. Our goal here is to begin conversations about shifting the government's response from a causal to a presumptive association model. Hopefully, with time and discussion, answers to the many outstanding policy and implementation questions will emerge. The existing federal response examples described here offer insights into implementing a standardized presumptive association approach. Furthermore, communities like East Palestine that have faced environmental chemical exposures have valuable expertise to provide in the design and execution of such an approach. Establishing leadership councils that allow community leaders in impacted areas to participate in decision-making will help establish what communities want and need after an exposure. A collaborative effort will be necessary to implement a presumptive association approach that engages and involves the impacted community to effectively protect public health.

CONCLUSION

When communities are exposed to toxic chemicals in the environment and subsequently develop health conditions, government action is limited unless there is proof that these health conditions are caused by the specific chemical exposure. However, because of many scientific uncertainties, critical information required to make causal determinations is rarely available. As a result, the government has rarely adequately acted in communities to protect public health. A presumptive association approach to toxic chemical exposures would provide the government with a way to make decisions, act, and protect public health in the face of scientific uncertainty. This approach would use existing scientific information to aid people who were (1) present at the time and place of chemical exposure and (2)

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Environ. Sci. Technol. XXXX, XXX, XXX−XXX

subsequently developed health conditions known or suspected to be associated with exposure to those chemicals. The government has previously recognized that critical scientific information is missing or incomplete making it necessary to make presumptions about exposure leading to health problems suffered by 9/11 survivors and first responders, soldiers exposed to emissions from burn pits, Marines exposed to contaminated drinking water at Camp Lejeune, and in other instances. Assisting those who fulfill these criteria without having to prove causation would create a clear, standardized government response to toxic chemical exposures and better protect public health.

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The authors declare no competing financial interest.

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Environ. Sci. Technol. XXXX, XXX, XXX−XXX