

Response Unequal Protection

Investigating Health Impacts in Communities Exposed to Toxic Chemicals from Environmental Contaminants Proposed Health Investigation Approach

The Center for Health, Environment & Justice started the Unequal Response, Unequal Protection campaign to address the federal government's ongoing failure to protect communities exposed to toxic chemicals. This failure stems from the lack of a structured federal response capacity and inadequate scientific methods for investigating health outcomes related to exposures to toxic chemicals. Health investigations typically take years to complete and often result in an uncoordinated multi-agency investigation with little attention given to the specific health concerns of local residents. Rarely do these investigations generate meaningful action to protect communities. Additionally, the failure of the current response has a disparate impact on low-wealth populations and communities of color who are already disproportionately impacted by environmental hazards.

CHEJ set out to address the lack of capacity and effective investigative tools by bringing together community leaders, scientists, and policy analysts to identify and develop a community-driven public health response model for investigating health Impacts resulting from areawide environmental contamination. The overall goal of this effort is to secure a timely community-driven investigation of health impacts from chemical exposures in communities that results in meaningful action for those affected.

CHEJ held a series of meetings with community leaders from contaminated communities and scientists and health professionals to discuss what a community driven response would look like. These meetings were highly effective in providing the opportunity for these community leaders and health professionals to discuss the problems with the way health investigations are currently conducted, to brainstorm ways to improve the process, and to create a new vision of what a community-driven health investigation process should look like.

Background

A. Federal Response to Epidemics, Contaminated Food and Disasters

There currently are existing structured responses for many public health threats. If the public is exposed to an infectious disease or contaminated food source, there is an immediate and urgent response by federal agencies to investigate, identify, and eliminate the exposure. Both the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) have

programs in place with clear proactive protocols that can be activated to respond immediately. The National Institute for Environmental Health Sciences (NIEHS) and the U.S. Environmental Protection Agency (EPA) also have structured response programs in place.

B. Federal Response to Area-wide Environmental Contamination

In the case of a neighborhood or entire community exposed to environmental chemicals, the government's response is not clear or well defined. If the public is at risk from exposure to widespread toxic chemicals in a community, there is no rapid response capacity and the ensuing investigation is uncoordinated and often superficial. These investigations typically take years to complete and rarely lead to action. Even if an investigation determines that a disease cluster does exist, there are no guidelines for federal or state agencies on how to effectively respond. This has often resulted in government taking no action to address or further investigate elevated rates of disease or to prevent further harm. Meanwhile, the community is left with many unanswered questions and with many, often serious, health problems.

C. Developing a Community Driven Health Investigation Approach

CHEJ held virtual meetings with community leaders, scientists, and health professionals over several months. The community leaders were largely from communities or organizations that had experienced health investigations in some capacity. The health professionals had a wide range of experience in evaluating health concerns in communities. Many of the scientists and health professionals were recommended by the community leaders. The overwhelming theme coming out of both sets of meetings was the vital importance of the community's presence in any health investigation process. Both groups agreed that health investigations should be driven by impacted community members and that they should be involved in every step of the process.

The ideas raised and developed during these meetings are captured in a separate background document that is available upon request. A short overview of the highlights of these discussions and conclusions is included below.

The community meetings began with a recounting of the many problems experienced by community leaders with the current approach to health investigations. Several key concerns raised were:

- The long time it takes for the government to respond or take action.
- Many government studies are poorly designed and often cannot answer the questions that people have about health problems in their community.
- The reliance on existing data, primarily environmental testing data, generated by other agencies. This data is often gathered to answer completely different research questions, yet it is shoehorned to evaluate the health effects in communities.
- The lack of action to address the problem and prevent further harm once the investigation has been completed.

Community leaders identified several overarching principles to guide the investigation process:

- The value of human life is the basis for environmental protection.
- No preventable death is acceptable.
- Assume chemicals are dangerous until proven safe.
- Community and traditional knowledge and culture is valued equally with academic scientific knowledge.
- Community voices are critical to understanding a local health concern and to defining the goal(s) of a health investigation.

The community leaders also discussed key elements to a community driven health investigation many of which were centered around the importance of involving community members from the very beginning of the investigation and in every step of the process. There was a strong sense that community members should have equal standing to scientists, experts and government officials in the decision-making process and that incorporating local, cultural and traditional knowledge was critical to the success of the investigation.

The initial meetings of the scientists and health professionals focused on unresolved science issues that impact the ability to determine the cause of adverse health outcomes in communities exposed to toxic chemicals. These challenges included:

- The lack of scientific understanding and knowledge about health effects resulting from exposures to low level mixtures of toxic chemicals.
- Inadequate methods for measuring and evaluating health effects resulting from exposures to low level mixtures of toxic chemicals in community settings.
- The problem of having to evaluate both acute and chronic health outcomes in the same exposure scenario.
- A lack of transparency about how choices are made and information is used by government decision makers who have their own priorities that includes economic trade-offs.
- The ethical and moral issues of not taking action until health outcomes can be linked to environmental exposure to toxic chemicals.

The scientists and health professionals offered a number of approaches to guide scientific analyses in the face of these challenges and uncertainties and a number of suggestions to address these uncertainties over the long term. Several of the key suggestions to address these challenges and uncertainties included:

- Use of a hazard-based approach to evaluate risks in place of risk assessment. This hazard-based approach has taken the form of the Presumptive Association analysis.
- Use of scientific judgment and a weight-of-the-evidence approach to determine public health risks and take appropriate action.
- Acknowledging that it is not necessary or appropriate to wait for scientific certainty or proof to act.
- Taking a precautionary approach to reduce exposures and protect people while carrying out the investigation and collecting data/information.

- Acknowledging the significant limitations in current scientific approaches used to answer questions raised about health problems in communities.

The discussion with both community leaders and scientists created three major pillars for our community-driven health investigation approach:

- Given the scale and scope of the problem of contamination and toxics in the environment around communities in the US, the only viable response entity is a Federal Agency. The Agency for Toxic Substances and Disease Registry (ATSDR) already is charged with protecting communities from environmental chemical exposure, so they are the most logical entity to implement our community-driven health investigation.
- The hazard-based approach that will use a weight-of-the-evidence style to determine public health risks will be a Presumptive Association approach similar to that used by ATSDR at the Camp Lejeune Marine Corps Base.
- The affected community must be involved and in charge of the decisions that affect their health. As a result, the decision-making power throughout the community-driven health investigation will shift away from federal agencies to the community in the form of a Community Leadership Team (CLT).

This report represents our best efforts to provide a document that reflects the work of a group of community leaders, scientists, and health professionals to develop what a community-driven health investigation looks like. The report remains a living document.

A Proposed Community Driven Health Investigation Approach for Evaluating Health Impacts in Communities Exposed to Toxic Chemicals

Overview

The community-driven health investigation developed by CHEJ has three main pillars that ensure the impartiality and efficacy of the process. The first is an affirmation of the large scale of the problem faced. Environmental contamination by toxics around communities in the country is a massive problem that can only be tackled by a centralized federal response. The Agency for Toxic Substances and Disease Registry (ATSDR) is already charged by congress to “prevent or mitigate the adverse human health effects and diminished quality of life that result from exposure to hazardous substances in the environment”, so they are the most logical vehicle to implement our investigation. The second is a paradigm shift – moving away from expecting the community to prove that their adverse health effects are caused by a particular chemical exposure to a *Presumptive Association* approach that puts people first. The third and final pillar is the conception of the *Community Leadership Team (CLT)*. This body will be composed in its entirety by affected community members and it will have sole authority in dictating the direction of the health investigation and the actions taken to mitigate the problems.

The process itself is composed of a 3-step pre-investigation phase and an 8-step health investigation phase. The following table provides an overview of the different steps in each phase.

Table 1 – Community-Driven Health Investigation Approach Overview

| Pre-Investigation Phase | |
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| CHEJ Response Phase | Description |
| Request Response Through Intake Form | A standardized intake form is completed by the affected community members and submitted to ATSDR. |
| ATSDR Initial Contact Timeline | ATSDR must initiate an evaluation of the request and provide a response no longer than 30 days after submission. |
| Decision to Pursue Investigation/Response | A joint decision made by the community members and ATSDR; ATSDR will access and share local, state, and federal data on pollution sources, health statistics and other relevant information; a decision on whether to pursue a health investigation or not will be made within 60 days from the date the intake form was received. |
| Investigation Phase | |
| CHEJ Response Phases | CHEJ Response Phases |
| Step 1: Formation of Community Leadership Team (CLT) & Independent Presumptive Review Board (PRB) | <ul style="list-style-type: none"> - The CLT is the decision-making body that drives the health investigation. The ATSDR response team will coordinate its assembly and aid the CLT in moving the steps of the investigation. - The PRB is an independent committee of scientists (toxicologists, epidemiologists, etc.) who will use the Presumptive Association approach to analyze the chemicals present in the community and the health effects seen. |
| Step 2: Defining Area of Concern | The CLT will define the area impacted by the contamination and is the subject of the investigation. This determination will be done in collaboration with the larger community. This area will be the target for gathering and evaluating existing environmental testing and health data, and for determining if additional testing is needed. |
| Step 3: Defining the Purpose of the Investigation | The CLT will seek and discuss the health questions raised by the community and use this input to define the goals of the investigation and determine what questions the investigation needs to answer. |

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| Step 4: Community Outreach | CLT will oversee the dissemination of information to the community. The goal of the outreach program will be to keep the community informed on the work of the CLT throughout the investigation process. Outreach materials will include environmental testing and health data, information on pollution sources, potential routes of exposure, etc. |
| Step 5: Collect Existing Data on Environmental Contamination & Health Problems. PRB Begins Presumptive Review Process | The CLT will gather all relevant health and environmental data and information available in the area of concern. This data can come in the form of: environmental testing data; health data and reports; observations, experiences and interpretations of community members; permit and other emissions data from potential pollution sources; etc. This data must be forwarded to the PRB to begin the presumptive association review process. |
| Step 6: Evaluate Existing Data & Collect New Data if Needed | Upon gathering all available data, an analysis will be done that will begin to paint a picture of the potential chemical hazard. At this point, if the data available is insufficient to characterize the potential chemical hazard adequately, the CLT will request that ATSDR collect new data (environmental testing, health data, etc.) as needed. As soon as this new data becomes available, it must be forwarded to the PRB. |
| Step 7: Evaluate All Data Along with Presumptive Analysis and Determine if Action is Warranted | Once all relevant data has been gathered, it must be analyzed to create a clear assessment of the chemical contamination and the effects on the health of the community. This evaluation will be supplemented by a report provided PRB. This report will be created based on the <i>Presumptive Association</i> approach. |
| Step 8: Take Action to Reduce Exposures | If the data evaluation suggests a chemical hazard to the health of the community exists, the CLT will determine the best action to remove or minimize the exposure. The CLT will provide a list of action options |

Pre-investigation Phase

The process of initiating a health investigation by ATSDR will originate from a concerned community. The request will be done through an Intake Form that will make the case for an investigation. The intake form asks questions about the makeup of the community, pollution and contamination sources, exposures, and the health problems people have. It also includes a summary of the situation. Five people from the community will need to sign the intake form to demonstrate a community wide concern. A sample intake form is included as Appendix A (link to intake form).

This intake form was designed to create a clear process by which community members can request a health investigation. The form invites people to tell the story of their community,

their environment, and the health problems that have been observed. This allows people with different types of communities, pollution, and health effects an opportunity to request an investigation and provide valuable, specific information about their situation. The combination of this on-the-ground information along with some easily available statistics about a community will be the best way to make a case for a health investigation. The flexibility of this intake form ensures that if certain information is not known or relevant to a community, it will not affect the outcome.

ATSDR will provide the intake form and answer any questions communities may have about it. Once the form is submitted, the ATSDR staff will review the responses and reach out to the community petitioners to begin a dialog within 30 days from when the form was submitted.

In reaching out to the community petitioners, the ATSDR staff member or team who responds to the intake form will ask questions to better understand the concerns raised in the form. ATSDR will also use all resources available to them to acquire additional information related to potential environmental health hazards in the community. They will have ready access to data on pollution sources, health statistics and other information relevant to the community and the exposure scenario in question. Information sources will include local and state environmental and health agency databases as well federal programs such as the EPA's ECHO data base and its Toxic Release Inventory. Key information might include suspected or known industrial releases or areas of contamination, known environmental hazards in the community, information on suspected health outcomes that may be related, or other helpful information such as evidence in the form of test results.

All this information will be considered in evaluating the intake form. ATSDR will share this additional information with the community petitioners and together they will develop a picture of what might be going on in the community.

In considering the community's responses to questions on the intake form, particularly in terms of the health effects and potential chemical exposures, it is incumbent on ATSDR's responding staff to recognize and acknowledge the complexities and uncertainties in the scientific understanding of the link between adverse health outcomes and environmental exposures. These complexities include limited understanding of the impacts of exposures to multiple chemicals, the lack of information on exposures such as the concentration of the contaminants and the length of exposures, varying sensitivities and vulnerabilities in people and cumulative effects over time. These limitations and lack of information shouldn't be the reason to defer from initiating a health investigation or to refrain from taking action.

If there is sufficient concern or uncertainty about potential exposures and health effects described in the intake form, then a clear and transparent decision on whether or not to initiate a health investigation will be reached jointly by the community petitioners and ATSDR. This decision should be made in no more than 60 days from the date of the initial request.

Based on the information provided in the application as well as information acquired by ATSDR, factors that would be considered in deciding whether to go forward will include:

- Data that indicate the presence of an overburdened community.
- The finding of multiple pollution or contamination sources with exposure pathways leading to where people live, work, and/or play in the community.
- Reasonable concern for public health generated by reports of adverse health effects or disease occurring in the community.

If a decision is made not to initiate an investigation, the community petitioners will have the option to appeal the decision to ATSDR's ombudsman. The request, the decision, and the reason for the decision will be made public and kept with the records of the request. Any information collected in this pre-investigation phase will be stored in a publicly available database and maintained by ATSDR for future use. This information will be re-evaluated should new information become available that supports the concerns initially raised by the requestor.

Health Investigation Phase

Once the decision has been made to initiate an investigation, a response team will be dispatched from ATSDR. The response team will notify local jurisdictions as well as the local and state health departments and the state public health officer that they are preparing to go to the community to initiate an investigation. The response team will have the legal authority to respond and will take the lead in putting together the CLT. There is no question about interagency or intergovernmental jurisdiction, that is, who is responsible for responding to the question(s) being raised. No formal invitation from the local or state government is needed for the response team to go to a community and begin the investigation. However, the local and state environmental agencies would likely be an important source of information and knowledge about the situation in question, so the response team should establish contact with these agencies and develop a collegial rapport.

Overview

The investigation phase is composed of 9 distinct steps that are fleshed out in detail in the following section. The first step, the formation of the CLT and the PRB, is perhaps the most important one because sets the leadership and expertise needed to effectively move the process forward. After these steps, both bodies will diverge and work in different areas – the CLT overseeing each step of the investigation and the PRB creating a detailed presumptive analysis using the data they receive from the CLT.

The investigation itself will then proceed to determining the scope of the investigation by defining the area of concern in the community and defining the purpose of the investigation. As part of these two steps, the CLT and any advisors involved, such as scientists and government

officials, should build a relationship with the community at large based on mutual respect and cross learning. Out of this relationship building will emerge a level of trust and connection that will guide the rest of the investigation.

The next step will involve developing an outreach plan to keep the community at large updated about the investigation. This step is key to maintaining the trust of the community and will make the next part of the investigation much easier to navigate.

The next steps will involve data collection and analysis. All existing data from environmental testing to word of mouth from community members will be collected and analyzed. Data gaps will be identified and new data will be collected as needed. All this information will be sent to the PRB to inform their presumptive analysis.

Finally, when all data has been collected and analyzed, and the presumptive report from the PRB is reviewed by the CLT, a determination will be made of the level of hazard being faced by the community. If a significant hazard is determined, the CLT will recommend appropriate remedy actions to address the problem and protect the impacted community.

For each of these steps, there is a binding timeline that limits how long each step can take. An overview of the steps and an accompanying timeline is shown below in Table 1. Each of these steps is discussed in detail in the next section. The timelines included here are not discrete periods of time, but rather overlapping and concurrent time frames for decision-making intended to ensure that the process continues to move along. The timeframe for the investigation is 11 to 13 months. The overall timeframe for the entire process including the consideration of the Health Investigation Request Intake Form is 13 to 16 months.

Table 1 - Timeline for Response*

| Phase | Step | Time Period | Overall Timeline |
|-----------------------|---|--|-------------------------|
| Pre- Investigation | Submission of Health Investigation Request Intake Form | ATSDR has 30 days to respond. | 30 days |
| | ATSDR and petitioners decide to pursue an investigation | ATSDR has 60 days from the receipt of the intake form to make the decision. | 60 days |
| Investigation | Formation of the Community Leadership Team and the Presumptive Review Board | ATSDR must form CLT within one month and PRB within 3 months of the start of the investigation | 3 months |

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|--|---|--------------|
| Defining the area of concern | To be completed within <u>one month</u> . | 4 months |
| Define the Purpose of the Investigation | To be completed within <u>one month</u> . | 5 months |
| Community Outreach Plan | Outreach plan to be completed within <u>2 weeks</u> . Outreach itself will be ongoing. | 5 months |
| Collect Existing Data on Environmental Contamination & Health Problems | To be completed within <u>one month</u> . | 6 months |
| Evaluate Existing Data & Collect New Data if Necessary | To be completed within <u>3 months</u> | 6-9 months |
| Evaluate All Data Along with Presumptive Analysis and Determine if Action is Warranted | To be completed within <u>2 weeks</u> . | 7-10 months |
| Take Action to Reduce Exposures | To be completed within <u>5 months</u> . | 13-16 months |

*The timeframes included in this table are meant to reflect a continuous sequence of events that are often overlapping and concurrent in time.

1. Formation of the Community Leadership Team & Formation of the Presumptive Review Board (To be completed within 1 month of the start of the investigation)

The first step in the investigation phase will be the formation of two key committees – the Community Leadership Team (CLT) and the Presumptive Review Board (PRB). The CLT will require the formation of an advisory team of ATSDR staff, other experts, and government officials. It is important to note that both the CLT and the PRB must be formed simultaneously to expedite the investigation phase.

Community Leadership Team

The CLT will be the main decision-making body throughout the investigation phase, and it will be composed entirely of community members who are affected by the chemical contamination in the neighborhood. An open and transparent process, which will be expanded upon further down in this section, will be used to select members of this leadership group. The CLT should be

formed within 30 days of the decision to initiate an investigation.¹ The formation of the CLT will be supervised by the ATSDR response team and all the community members who submitted the petition to initiate a health investigation.

The CLT will place the community's leadership and its members at the center of its decision making from the very beginning and establish an outreach plan that will operate throughout the investigation process to share information with community members and the public. The initial work of this guiding body will be to build a relationship between community members, the response team and other participating scientists, experts and government officials, who will be used throughout the investigation in an advisory role, based on mutual respect and sharing experiences.

Make-up of Community Leadership Team: The CLT will be made up exclusively of residents who are impacted by the potential chemical contamination in their community. Initially, the CLT will be composed of 9 individuals, but this number can increase in increments of 2 to allow for majority decisions to remain. The community members who submitted the intake form will be given priority in joining the CLT, and the remaining slots will be open to all other community members who may be interested in participating.

The process for selecting the remaining members of the CLT will be supervised by the ATSDR response team as well as the original community petitioners. An outreach plan for informing the community about the positions in the CLT, as well as a set of in-person community meetings should be part of the selection process. In selecting the remaining members of the CLT, it is paramount to include people who represent the social, economic, and geographic diversity of the community.

CLT Advisory Team: To aid the CLT in understanding technical information and making informed decisions, an advisory team will be created composed of:

- ATSDR response team members
- Public & environmental health experts – toxicologists, epidemiologists, GIS specialists, etc.
- Government officials – federal, state, or local
- Health educators and environmental justice experts

These individuals will serve as expert resources to the CLT, helping better understand environmental and health testing results and technical reports, and helping design communication strategies and remediation activities. It is important to note that, while this advisory team will provide key data analysis and technical viewpoints, they hold no voting power; all of the decision-making power is reserved exclusively to the members of the CLT.

ATSDR will provide some of the experts that will play a role in providing technical advice to the CLT. The community may also choose to include epidemiologists, toxicologists, or other public health experts of their choosing. For this purpose, the ATSDR response team will provide the CLT with a list of local public health experts that may be available to consult, or the community may nominate other experts of their choosing. Additionally, government officials who have an interest in the well-being of the community may participate in the advisory team. These government officials may also suggest scientists from the local health or environmental department to be a part of the advisory group.

Finally, it may also be valuable to include experts with experience in social and environmental justice to help address the larger needs of the impacted community including the development of local leadership. Consideration should be given to including a health educator, communicator, or science translation expert as part of the advisory team to help accurately translate information for members of the group and the public in easy-to-understand language. This person could also help advise the CLT with regards to the best format for disseminating information to the larger community and the type of outreach needed. If a decision is made to hire someone with these skills, this person should be independent of government.

It is important to note that the makeup of this advisory team is not fixed. Members of the advisory team may come and go based on the needs of the CLT at any particular step of the investigation phase. The CLT has sole authority to determine what experts are part of the advisory team.

Functions of the Community Leadership Team: The CLT will function as the central operating hub for the investigation. All data collected and generated during the investigation will be reported to and maintained by the CLT. No personal identifiers should be included in any of the data sharing. The CLT will also approve any and all activities concerning the investigation phase by the ATSDR response team as well as any other federal or local government agencies.

The CLT will establish operating rules that are similar to Institutional Review Board (IRB) or Community-Based Research Agreement guidelines that will ensure the community is centered in the decision-making process throughout the investigation. These rules will ensure that the community has all the authority in the decision-making process, has ownership of data collected in the investigation, is kept informed and engaged, and that any activities during the investigation do not cause harm to the community.

The CLT will establish a communications network early on to keep community members, government officials, and the general public informed and connected. This network must establish an infrastructure that allows the public to report contamination or suspected chemically-associated health conditions directly to the CLT and must create a comprehensive system for collecting and distributing information. Input from the relevant experts from the advisory team will be important in establishing an efficient communication network.

Listening Sessions: The CLT will conduct listening sessions where local, cultural and traditional knowledge can be gathered to significantly contribute to the investigation process (no one knows the community better than the people who live there), such as by identifying places that need to be tested. During the formation of the CLT, these listening sessions can be useful tools to select its members.

After the CLT is formed, these listening sessions will be crucial for the CLT to know what actions community members might want, such as testing certain areas or making medical or screening tests (blood, urine, etc.) available to residents, and to stay up to date on any new developments in the health of the community. Additionally, these listening sessions will be excellent opportunities for scientists, experts and government officials from the CLT advisory team to learn about the community's concerns and to understand their local, cultural and traditional knowledge.

Technical Assistance: As mentioned previously, the community may want to include public health scientists of their choosing in the advisory team. This option is important to make sure that the CLT can build trust in the advisory team and be certain that the process is effective and transparent. Funds should be made available to the community to hire expert(s) including a health scientist of their choosing. The main role of these experts will be to keep the CLT informed on the technical aspects of the investigation and the methods used to assess health impacts. This program could be modelled after the US Environmental Protection Agency's (EPA) Technical Assistance Grants (TAG) program that provides up to \$50,000 to local grassroots community organizations at Superfund sites in order to hire independent technical support for local residents. This grant program should operate with a more simplified granting process than the EPA TAG program.

Presumptive Review Board

The Presumptive Review Board (PRB) will be an independent team of toxicologists and public health experts who will perform the Presumptive Association analysis of the chemicals present in the community and the health effects seen. This analysis will follow a strict protocol that will be outlined in Appendix B (link to Appendix B). It is imperative that members of the PRB follow the guidelines established in the protocol since the approach is significantly different than conventional risk assessment.

Makeup of the Presumptive Board: The PRB must be composed of scientists who have no ties to ATSDR or to the chemical industry. They must remain neutral and unbiased so that their analysis can be considered valid by all parties involved. This requirement may seem easy to fulfill, but it can be extremely difficult to discern subtle connections to industry that can compromise a scientist's judgement. For this reason, a transparent and diligent process must be established by ATSDR for the assembly of this committee. Among those who can be considered for participation in the PRB are members of academia, as well as experts from organizations such as the National Academy of Sciences.

Functions of the Presumptive Review Board: The PRB's main function is to follow the Presumptive Association protocol and use their expertise to develop a report that details chemicals found in the community's environment and the health effects that are associated with exposure to them. This report will be provided to the CLT and used to select the appropriate remediation actions to protect the health of the community.

2. Define the Area of Concern (1 month and to be completed within 2 months of the start of the investigation)

The Community Leadership Team will define the area that has been impacted by the contamination and is the subject of the investigation. This determination will be done in collaboration with the larger community, through listening sessions and one-on-one conversations. In addition, it will be useful to schedule a tour of the area for the CLT and for the experts that are part of the CLT advisory team. This will help everyone become familiar with the area and make the process of defining the area of concern easier.

The area of concern will be the target location for gathering and evaluating existing environmental testing and health data, and for determining if additional testing is needed. This area will also be the target of communication outreach efforts to ensure everyone in it is informed about the process. Because chemicals can travel in the environment to different extents based on their specific properties, surrounding infrastructure, and routes of exposure, it is important to recognize that the area of concern may not be a contiguous geographical area where the chemical was released into the environment. Care must be taken to revisit the designation of the area of concern if and when new information about exposures or health outcomes comes to light.

3. Define the Purpose of the Investigation (1 month and to be completed within 3 months of the start of the investigation)

Following the listening sessions, meetings with community members and tour of the area, the CLT will discuss the health questions raised by the community and define the purpose and goal(s) of the investigation. This process will determine what questions the investigation needs to answer. The investigation should focus on the cumulative health impacts from all chemicals identified in the area of concern, not just contaminants of interest or some subset of the identified contaminants (such as chemicals of concern). The investigation should also take into consideration the need for long-term follow-up due to issues such as latency and diagnostic difficulties for cancer and other health outcomes. It is essential that the community as a whole, the ATSDR response team and the CLT all agree on the questions the investigation needs to answer and that everyone is on the same page.

4. Develop Outreach Plan to the Community (2 weeks and to be completed within 3 months of the start of the investigation)

The CLT will be responsible for developing an outreach program that keeps the general community informed on the work of the CLT throughout the investigation process. Although 2 weeks are allotted for the development of this plan, the outreach itself will be ongoing throughout the rest of the investigation. The health educator communicator or research translator in the CLT advisory team can provide valuable input in designing the outreach program. Some of the responsibilities of the program will include:

- Distribution of all data identified and collected during the investigation including environmental testing and health data and information on potential sources of pollution and contamination.
- Preparing and distributing maps showing the area of concern with summarized health and environmental testing results.
- Preparing and distributing fact sheets on information identified during the investigation such as identified pathways of exposure and the toxicity of key contaminants identified in the area of concern.
- Distributing newsletters or communications where updates on the progress of the investigation are provided to the community

The fact sheets, newsletters, and other material generated will be written in language easily understood by the readers in the area of concern and be available in multiple languages as appropriate. All the data and information generated should be made available on a website and provided in hard copy upon request. The health educator can help prepare documents and information in easy-to-understand language (in multiple languages as appropriate).

The CLT will set up two-way educational opportunities whereby community members can inform subject experts and other members of the CLT advisory team about new or overlooked matters and subject experts can share their unique expertise with community members. Providing ongoing educational resources and opportunities for the impacted community will be an important part of the success of the investigation. This could include training programs to inform residents about environmental hazards, testing results and other issues of interest. Engaging, educating, and informing health care providers can also be part of this effort.

5. Collect Existing Data on Environmental Contamination and Health Problems (1 month and to be completed within 4 months of the start of the investigation)

The CLT will gather all relevant health and environmental data and information available in the area of concern. As part of this process, the group will consider local culture, traditional

knowledge, and what was learned from the community visits and listening sessions. This process should include:

- Gathering and analyzing existing environmental testing data within the area of concern.
- Gathering and analyzing existing health data and health reports within the area of concern.
- Gathering and analyzing the observations, experiences and interpretations of community members linking environmental testing data with health data. This potentially can help determine where additional testing is needed.
- Identifying potential source(s) of contamination.
- Identifying existing and potential routes of exposure.
- Establishing whether a mixture of chemicals is present in the air, water, and/or soil for which the cumulative combined health effects are a concern.

Data Analysis: The collected data will be analyzed and presented in various ways to help evaluate the significance of the findings. These approaches can include:

- Constructing spatial maps of environmental sampling data that show contamination in soil, air, drinking water wells or other media.
- Constructing spatial maps of health outcome data.
- Constructing spatial maps of potential source(s) of pollution and areas of known or suspected contamination such as fracking wells, sources of discharges or emissions, hazardous waste disposal sites or other hazards.
- Cross referencing the health and environmental data as well as potential source(s) of pollution and areas of known/suspected contamination.
- Gathering as much information as possible on the onset of illness (symptoms, signs, or laboratory test positive) among affected persons.
- Establishing the period of exposure to the extent possible.
- Identifying timing of potentially related events, such as the opening of a new industrial plant, episodic air releases from an operating facility, etc.
- Identifying places of residence, occupation, and recreational activities.
- Identifying demographic information (age, sex, race/ethnicity), occupation, diagnoses, and other important characteristics of affected persons in the area of concern.
- Developing a chronological framework by collecting information about and ordering key events identified in the interviews and listening sessions.
- Identifying existing and potential routes of exposure.
- Establishing whether a mixture of chemicals is present in the air, water, and/or soil for which the cumulative and combined health effects are a concern.
- Developing a mechanism for storing/organizing data collected during the investigation.

Gathering the data in these formats can contribute to developing initial theories for identifying potential routes of exposure or possible sources or causes of the adverse health outcomes observed in the community. When considering the data and what it means, lack of evidence does not mean that there is evidence of no effect.

Part of this data gathering process will include collecting information on health problems in the area of concern. This information will be acquired during the community listening sessions, interviews, and tour of the impacted area. Other activities that can provide insight into the extent of the health problems in a community would include:

- Reviewing medical records and other pertinent clinical information.
- Confirming the results of laboratory testing and diagnoses made by local physicians (Depending on the results, unique subject experts may need to be consulted).
- Conducting clinical exams of affected people (by health care personnel not connected to any facility that may be contributing to pollution in the community) when indicated.

The CLT will also establish a comprehensive health tracking (surveillance) system that effectively collects, analyzes, and interprets adverse health outcomes in the impacted community. This system should consist of any health data gathered from the listening sessions and interviews and any additional data collected throughout the investigation. A tracking system is necessary to proactively detect chemical exposures and adverse health outcomes and to allow the CLT to better understand the relationship between exposures and health outcomes occurring in the community. The information will contribute to strategies to protect public health.

During this data gathering phase, the Community Leadership Team will gain an understanding of the impacted community including its local, cultural and traditional knowledge. Anecdotal knowledge can provide insights crucial for the development of appropriate questions, study designs and research methodologies and should be valued equally with academic scientific knowledge.

While collecting this information, the Community Leadership Team must keep in mind that some health effects may only manifest years or decades after the exposure. Furthermore, most people are exposed to more than one toxic chemical at a time, and even if the exposures themselves don't overlap, their long-term health effects may interact in complicated or unknown ways.

Presumptive Review: In this step, the PRB will initiate their analysis. The CLT will forward all available data to the PRB for their review to begin. The starting point of this analysis will be the data gathered and discussed during the pre-investigation phase. This includes all the anecdotal information provided by the petitioners in the intake form and in subsequent conversations with ATSDR, as well as all the data gathered by ATSDR from sources such as health agency databases and/or federal programs such as the EPA's ECHO database and its Toxic Release Inventory.

The data collected and analyzed in this step will fill in the remaining gaps, providing key health outcome information that will lead to the identification of common diseases as well as environmental testing data that will reveal the chemicals of concern.

The Presumptive Association review will continue through the remaining steps of the process in a parallel fashion to the investigation at the site. As the investigation continues, new data will likely become available. Any new data must be forwarded to the PRB to ensure that their review is as robust and comprehensive as possible.

6. Evaluate Existing Data & Collect New Data if Necessary (Up to 3 months and to be completed within 7 months of the start of the investigation)

Following the interviews; listening sessions; and gathering of all relevant health and environmental data and information, the CLT will determine whether the existing data is sufficient and adequate to properly evaluate the public health risks posed by the environmental contamination. The CLT advisory team will play a key role in evaluating the completeness of the health and environmental contamination data, and in advising the CLT on where any gaps are. Based on this evaluation, the CLT will recommend additional testing as needed. This recommendation will include specifics such as where to collect the additional samples, how many samples to collect, the media from which the samples should be taken, when and how often the samples should be collected, what substances to look for, and what sampling methods to use. ATSDR will then follow these recommendations and perform any additional environmental testing or health evaluations in a timely manner. Any new data that is collected needs to be promptly provided to the PRB.

7. Evaluate All Data Along with Presumptive Analysis and Determine if Action is Warranted (2 weeks and to be completed within 7 months of the start of the investigation)

In this step, all existing health and environmental data will be evaluated in conjunction with any new data that was collected and analyzed. Additionally, the PRB will provide their Presumptive Analysis report to the CLT. This report will establish the associations between chemicals found in the community and the health problems that can result from exposure to them. The CLT will use both of these tools to follow a weight-of-the-evidence approach to determine if a public health threat exists in the community, and if so, what kind of action is needed to address it.

The input of the CLT advisory team about the data evaluation and the Presumptive Analysis report will be valuable to the CLT. However, it is imperative that the evaluation of the level of the public health hazard in the community be taken solely by the CLT without any coercion from any member of the advisory team or any third party. The integrity of this process rests on assuring that the CLT alone is the decision-making body of the investigation.

8. Take Action to Reduce Exposures (5 months and to be completed within 13 months of the start of the investigation)

Once the CLT has characterized the public health threat in the community and decided that it is serious enough to take action, the CLT will transition to the step of selecting the appropriate remedy. The remedy selected must address the contamination established in the Presumptive Analysis report and be justified through the evaluation of all collected health and environmental data. This means that the remedy selected must address things like the exposure pathways identified, the emission sources, and all unknown factors that can contribute to increased exposure. The remedy selected must also prioritize safeguarding the health of the community immediately. This means that healthcare must be provided to address any lingering health effects that the community may be experiencing.

To aid the CLT in selecting the most appropriate remedy, Appendix C contains a list of potential remedy actions that have been taken or were proposed at other contaminated communities around the US. This list is not exhausting, but it provides a starting point for the CLT to build the correct remedy for their community.

Appendix A:
Health Investigation Request Intake Form

Name:

Address:

Phone number:

Email address:

Organization (if applicable):

Other community members signing on to the community intake form (name at least 4):

PART 1: WHAT IS HAPPENING IN YOUR COMMUNITY?

Overview

In 500 words or less, tell us the story of your community and why you need a health investigation. Describe the pollution that you believe is causing health problems, what health problems you think are related and what changes you'd like to see occur in your community. If you think photographs or videos will help document the pollution or health problems in your community, you can attach them here.

Pollution and/or Chemical Exposure

In order to understand what is happening in your community, we need you to define a geographic area that represents your community – it could be a zip code, a neighborhood you define with street boundaries, or all the area within one mile of the source of pollution. You may not be able to perfectly define your community this way, but doing so to the best of your ability is essential for completing this form. Please define the geographic area representing your community here:

Do your best to answer the following questions. Don't worry if you do not have answers to any of these questions or if the questions don't apply to your situation. Respond to those questions that make sense.

- What first brought your attention to the chemicals in your community? (For example: Did you smell something in the air? Was drinking water discolored? Was there a fire or explosion?)
- Where do you think the chemicals in your community are coming from? Is there more than one source? How do you know?
- Are the facilities causing the pollution/chemical exposure still operating?

- Have any of these facilities causing the pollution/chemical recently shut down?
- Have they been closed for at least 1 year?
- How do you think you're being exposed to these chemicals? Select all that apply:
 - Surface water
 - Groundwater
 - Drinking water
 - Farm runoff into waterways
 - Indoor air
 - Outdoor air
 - In the path of prevailing winds
 - Dust
 - Food supply - local farming
 - Food supply - household garden
 - Food supply - fish and wildlife
 - Soil
 - Fracking
- Are there other ways you are being exposed?
- Why do you think this is how you're being exposed? (For example: Did you hear about it on the news? Did your town or city hold a meeting about it? Did a neighbor tell you? Did a government agency or private company inform you or conduct a study?)
- Do you know what chemical(s) you're being exposed to?
- To the best of your knowledge, how long do you think these chemicals have been in your environment?
- Is there anything else about the location of the chemical source that increases people's risk of exposure from its emissions? (For example: is the chemical source on higher ground than the homes of the people exposed? Do the people exposed live downwind from the chemical source?)
- Are you aware of any environmental testing in your community? If so, do you know what entity did the testing and what entity has the results? (Note: we know that environmental testing may not always be conclusive or answer the questions a community has. If your community has had environmental testing, the decision to move forward with an investigation will not be made using only this data.)
- Is there environmental testing you think should be done but hasn't been?
- Has a local, state, or national agency ever investigated an industrial or polluting facility in your community? If so, which ones?
- Has there ever been an evacuation in your community because of a natural disaster (hurricanes, floods etc.) or environmental emergency (spills, toxic runoff, etc.)?
- Has an industrial facility in your community ever been evacuated for an emergency even if the surrounding residents were not?

Health Effects

- What health problems in the community do you think may be related to chemical exposure? Select all that apply:

| | |
|---|--|
| <ul style="list-style-type: none"> ➤ Autism ➤ Asthma and/or respiratory problems ➤ Behavioral changes ➤ Birth defects and/or developmental problems ➤ Blood and/or immune system problems ➤ Cancer ➤ Diabetes ➤ Digestive and/or liver problems | <ul style="list-style-type: none"> ➤ Eye irritation ➤ Hair loss ➤ Infant mortality ➤ Kidney/bladder problems ➤ Learning or memory problems ➤ Miscarriages ➤ Neurological disorders ➤ Physical movement problems ➤ Rashes ➤ Reproductive problems |
|---|--|

- Are there any other health problems that may be related to the chemical exposures?
- Do children and/or the elderly seem to be affected more than others?
- Are there any health problems you have observed in fish, wildlife, livestock, or pets that may be related to the chemical exposures?
- To the best of your knowledge, how long have you been aware of health problems in your community?
- Are there any health problems related to infectious diseases in the community?
- Has the community had Covid-19 infections? Have there been deaths from Covid -19 in the community?
- To the best of your knowledge, to what extent do these health problems affect people's ability to live, work, learn, pray, or play in your community?
- Has a health study, questionnaire, or interview ever been conducted in your community? If so, do you know what entity did the study and what entity has the results? (Note: we know that health studies may not always be conclusive or answer the questions a community has. If studies have been done in your community, the decision to move forward with an investigation will not be made using only this data.)
- If there is any other information you think may be important for this investigation, please provide it here.

PART 2: ADDITIONAL DETAILS ABOUT YOUR COMMUNITY

This section is optional and will be completed by the response entity. It is included here so that you know what information the response entity will be seeking. You are welcome to provide answers to any question in this section. You will not be disqualified from receiving an investigation based on the answers to these questions.

The answers to these questions can be found on the EPA's EJScreen and MyEnvironment tools. There will be a link to a guide on how to use this database and access this information.

[[hyperlink tutorial](#)]. If you are unable to use these tools to answer the questions, the response entity will fill them out for you based on the geographic area you defined as your community. You will not be disqualified from receiving an investigation if you cannot answer the questions yourself.

Demographic Information (can be found on EJScreen)

- Does your community have a higher percentage of residents under 5 years old than your state's average? (Your state's average can be found here: <https://www.indexmundi.com/facts/united-states/quick-facts/all-states/percent-of-population-under-5#map>)
- Does your community have a higher percentage of residents over 64 years old than your state's average? (Your state's average can be found here: <https://www.indexmundi.com/facts/united-states/quick-facts/all-states/percent-of-population-65-and-over#map>)
- Do more than 40% of residents in your community identify as people of color?
- Do more than 40% of households in your community have no adult who speaks English "very well"? (This is based on how households answer the question about English proficiency on the US Census)
- Are more than 35% of households in your community low income? (Low income is defined as below two times your state's poverty line)
- Are there day care centers in your community? If so, how far are they from the suspected source(s) of chemicals?
- Are there schools in your community? If so, how far are they from the suspected source(s) of chemicals?
- Are there hospitals in your community? If so, how far are they from the suspected source(s) of chemicals?
- Are there nursing homes in your community? If so, how far are they from the suspected source(s) of chemicals?

Environmental information (can be found on MyEnvironment)

- Please list any Superfund sites within one mile of your community.
- Please list any Department of Defense waste sites within one mile of your community. [This is not on MyEnvironment]
- Please list any incinerators within one mile of your community. [This is not on MyEnvironment]
- Please list any Brownfield or abandoned industrial sites within one mile of your community.
- Please list any RCRA permitted facilities (facilities that use, store, or release chemicals into the water or soil) within one mile of your community.
- Please list any deep well injection facilities within one mile of your community.
- Please list any nuclear power facilities within one mile of your community.
- Please list any Toxic Release Inventory sites within one mile of your community.
- Please list any Water Discharger sites within one mile of your community.
- Please list any impaired water bodies within one mile of your community.
- Please list any toxic, nuclear, or solid waste treatment, storage, or disposal facilities within one mile of your community.
- Are there highways within one mile of your community?
- Add any additional pollution sources that you are aware of.

Appendix B:
Presumptive Association Protocol

Presumptive Review Board

ATSDR will establish an independent scientific committee, the Presumptive Review Board (PRB), consisting primarily of environmental and/or occupational epidemiologists and at least one environmental/occupational toxicologist, all of whom have no ties to the chemical industry, the DOE or the DOD. The purpose of this committee will be to determine the strength of the evidence for causal associations between chemicals found in the environment and adverse health effects.

Data Sources

ATSDR will also establish a community oversight board that will review the work of PRB. This oversight committee will be a given site's Community Leadership Team (CLT). For work done at their specific site, the CLT will provide the PRB with environmental sampling data that will identify chemicals of concern. Additionally, the CLT will also provide health data that will identify illnesses and other adverse health impacts experienced by the residents of the site. From these data, the PRB will identify chemicals (or chemical classes) that should be evaluated through the Presumptive Review process.

Methodology

The PRB will perform an in-depth literature review of all the published information regarding the chemicals (or chemical classes) of concern found in a given site. After carefully and critically analyzing the literature, the PRB will classify the evidence into two categories:

- "At least as likely as not or above" (or equipoise or above) or
- "Insufficient evidence at present" (or currently below equipoise).

Exposure to a chemical will 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.

In assessing the potential health effects of a specific chemical (or specific chemical class), the PRB will review all the epidemiological evidence. Toxicological information that can provide insight on causal mechanisms will also be reviewed. For each chemical (or class of chemicals), adverse health effects will be selected for review if an epidemiological study of sufficient quality obtained an effect estimate for that health effect indicating a positive relationship (e.g., the odds ratio, risk ratio, hazard ratio, or SMR is greater than 1.0 or the regression coefficient is greater than zero). The study may evaluate the chemical itself as well as a proxy for the chemical (e.g., a study of dry-cleaning workers would be relevant to assess the health effects of

perchloroethylene or PCE exposure). A study will be considered of sufficient quality if the effect of biases tending to inflate or reduce the effect estimate was likely low.

In the assessment of the evidence for causality, the PRB will use as a guide the methodology ATSDR used in its "[Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases](#)." The PRB may conduct meta-analyses if necessary, and review assessments and meta-analyses conducted by EPA, IARC, NTP and academic researchers. The PRB will also apply key causal viewpoints associated with Hill, including the magnitude of the effect estimate (e.g., whether the odds ratio or risk ratio is greater than 1.10), temporal relationship (taking into account a relevant latency period), positive exposure-response trends (including trends that are not monotonic or linear), consistency of the findings within the study and between studies, and biological plausibility (taking into consideration available mechanistic information in support of a causal association). The PRB will also consider the potential for biases to reduce effect estimates. In particular, the PRB will be mindful that findings in a study that might appear to provide negative evidence could be the result of healthy worker effect biases, selection bias or confounding.

Appendix C:
Potential Remedies for CLT Consideration

TBD