

# 2022 ITRC Final Proposal Template

## Proposed Project Title

Identifying and Evaluating Chemicals of Emerging Concern

## Abstract

Regulatory agencies and the regulated community continue to be challenged by the ability to identify and address chemicals of emerging concern, even as the science of chemical testing advances and new information on chemical exposures and potential toxicity emerges. The emergence of chemicals discovered during widespread monitoring, with little or no toxicological data to put risk and “what does this mean” into context, will likely continue to be a future trend. Well-known chemicals can be difficult and costly to clean-up, however, trying to anticipate and/or identify chemicals that may emerge as contaminants of concern in the future (and in the timeframe demanded by the public) can create a new and different set of challenges. This proposed team is intended to provide a framework for anticipating and responding to emerging chemicals, largely building on lessons learned from the emergence of per- and poly-fluoroalkyl substances (PFAS) coupled with proactive identification of potential future chemicals.

## Problem Statement and Highlight the Importance to the States and to the Broader Environmental Community

Emerging chemicals are an issue that often demands immediate actions by state regulatory agencies. Once an emerging chemical is identified, public concern and interest may become elevated, requiring States to respond in a very short time period. Often actions need to be taken in the absence of sufficient toxicological data, and many of these actions will have a long lasting influence on future steps. Changing positions as new data and information become available can undermine the public’s confidence in the process and state actions, thereby adding a significant complication to the overall dynamic. This team understands that ITRC teams are already doing significant work on data management and risk communication. Using, as needed, the information from those teams, this team proposes to develop an approach which state regulatory agencies can use to anticipate, understand, and react to new chemical data in advance of impacts to public health and the environment, and possible public outrage.

Current state regulatory actions commonly focus on a limited set of chemicals compared to the thousands of chemicals currently produced, imported or used in manufacturing. USEPA and states have developed scientific positions on human health effects for only several hundred compounds. Given the thousands of chemicals used and produced world wide, USEPA has implemented several mechanisms to identify and evaluate emerging chemicals. This includes existing chemical risk evaluations and pre-manufacture notices under the Toxic Substances Control Act (TSCA) and the Unregulated Contaminant Monitoring Rule (UCMR) program under the Safe Drinking Water Act (SDWA). The results of these activities at the federal level often generate data and findings that have ripple effects down to the states, although there is no clear guidance or consensus on how states should evaluate or manage this information. 1,4-Dioxane and PFAS are two clear examples of this challenge. For these and other chemicals, there is no consensus process for individual states to use to monitor and evaluate new chemical data – with the goal of being aware (and potentially proactive) of arising issues. Nor is there a process to determine what the information means and decide if additional actions are necessary to address potential exposures and

toxicity. Significantly, these activities do not happen in a vacuum, but are accompanied by interest and input from the public. Frameworks and processes that can be used as examples by this team include those presented by the Department of Defense (Bass and Rak) and with the book *Emerging Contaminants: Anticipating Developments* (Sellers, Nelson, Weinberg, 2019).

For this proposal, emerging chemicals are defined as including the following: (1) a chemical that previously had not been evaluated under any state or federal site investigation and remediation program and has limited toxicity and exposure data and analytical testing methods (e.g., PFOA and PFOS); (2) a chemical that has been identified, has some toxicity and exposure data, but is not routinely regulated or included in sampling programs (e.g., 1,4-dioxane); and (3) an existing chemical that is currently regulated with existing toxicity and exposure information, but new information suggests changes to toxicity and/or exposure (e.g., ethylene oxide). This definition is consistent with other publications that state that an emerging chemical is “a chemical or material that is characterized by a perceived or real threat to human health or the environment with no published health standard, or an evolving standard” (Department of Navy 2018). For this team, the defining of an emerging chemical into one of three groups allows for the development of specific recommendations and approaches, based on the amount of available data.

The overall objectives of this proposed ITRC team will be to develop a series of Fact Sheets (each estimated to range between 5 and 10 pages) that identifies and addresses how states can track and identify chemicals of emerging concern. The Fact Sheets would also address the variables that lead to the identification of chemicals of emerging concern and provide parameters for evaluating these various factors including the potential for a chemical to present a widespread risk. Significant risk of an emerging chemical depends upon a complex mix of variables: the extent of release, permitted and otherwise; fate and transport in the environment and potential for exposure; hazards to human health and the ecosystem. Risk management considerations may include the ability to detect a contaminant, and the balance of risks and rewards associated with the use of the chemical. As these issues arise, there is no available framework for understanding when a particular chemical may require action by a state regulatory agency.

This proposed ITRC team intends to focus on understanding and evaluating emerging chemicals by providing a web-based resource (schematic showing how these Fact Sheets are interlinked in the overall process) for state agencies to use when determining how to identify and/or respond to new or emerging chemicals found in soil or groundwater. With an outline for how to evaluate and react to new data, state regulatory agencies can better plan and put processes in place, as appropriate. Using key examples and lessons learned from PFAS and 1,4-dioxane (and other chemicals as identified by the team), the team will develop a framework and associated processes that can be used by state regulatory agencies to review and understand available data, determine data gaps, and identify what additional data may be needed. Our intent is to create a framework that focuses on the key data needed to understand emerging chemicals. Using this framework, Agencies that do not have emerging chemical programs can start to better understand new chemical needs in anticipation of potential future activities that may be required should these issues emerge. States and organizations with developed emerging chemical programs can also benefit, since this is an ever growing and evolving field.

As discussed above, the web-based resource will be in the format of a series of Fact Sheets connected together by a schematic outlining the overall process. Each Fact Sheet is expected to include text, flow charts, and tables to support the discussion and allow state regulatory agencies easy access to any of the specific topic areas. Overall, the web-based resource will explore the identification of emerging chemicals and cover the following topics:

1. Identification of monitoring programs. As noted above, USEPA has several monitoring programs including SDWA that could generate data that may be useful for identifying emerging chemicals. The team will identify all possible sources of data (including those across regulatory programs) that could be used to identify emerging chemicals. This may include regulatory programs at the state and federal level, scientific associations, industry groups, international organizations and studies, and non-governmental organizations. For Category 3 chemicals, this may be expanded to include identification of new or updated toxicity values or other information (i.e., lower detections through new analytical techniques).
2. Evaluation of key variables. Once monitoring data are identified, the team will review the factors that can be used to determine whether a chemical should be identified as an emerging chemical. These factors could include extent of exposure, relevance to state, perceived or actual concern for human health and/or the environment.
3. Data management and risk perception and communication. These topics are also key pieces of understanding and addressing emerging chemicals. This team is aware of the work already underway/completed by ITRC and will rely heavily on existing materials on these topics. The goal is simply to convey how the information already developed can be used to address emerging chemicals.

In summary, the web-based schematic/resource and associated Fact Sheets would provide a framework and associated process by which states and other environmental agencies can monitor and evaluate new emerging chemicals. The goal is to provide a resource that can be applied to any emerging chemical found in soil or groundwater. This would allow state agencies to start the process by which they can anticipate and stay ahead of issues related to emerging chemicals. Once these processes are in place, states can better manage resources and plan for changes in soil and groundwater clean ups. It is expected that it will take 12 to 18 months for the team to complete the work.

Audience: The intended audience of this project are individuals (i.e., state regulatory agencies) involved in evaluating chemical exposures and toxicity, and individuals that use and review soil and groundwater data including data from site investigation and remediation projects. These activities may occur at the state and/or federal level and are expected to include regulators, consultants and academia. This guidance would also be valuable to regulators and scientists working in other environmental programs who need to address emerging chemicals.

## **Project Deliverables**

Document product: Web-based resource/schematic and associated Fact Sheets to address the identification of emerging chemicals. We envision the following topics as Fact Sheets; however, if some become too long they can be split into two Fact Sheets.

- Identification of Potential Emerging Chemicals.
  - This would include identification of regulatory programs that monitor or test for new chemicals.
  - Summary of monitoring data collected under each of these programs including time frames of data collection
  - Extent/reach of monitoring data collection and representativeness to site investigation and remediation sites
  - Summary of programs, agencies, and other organizations that monitor and identify new toxicity or analytical methods

- Evaluation of Potential Risk.
  - Understanding the various factors to consider when identifying an emerging chemical including the extent of release, permitted and otherwise; fate and transport in the environment and potential for exposure; hazards to human health and the ecosystem; and the ability to detect a chemical
  - Identification of resources on identified potential emerging chemicals
  - Managing and organizing the data collected using already existing ITRC data management methods and approaches
- Preparing for Addressing Emerging Chemicals.
  - Methods for tracking and understanding the timing of when chemicals may emerge as a concern for the public
  - Risk perception and communication of emerging chemicals using existing ITRC materials

The web-based resource will consist of a schematic that connects a series of Fact Sheets into an overall process, with each Fact Sheet expected to be 5 to 10 pages long including flowcharts, tables and text. The web-based resource would be supported by a video explaining the framework/process developed.

## **References**

Bass, No., Rak, A. "Evaluating Emerging Contaminant Issues within DoD". Retrieved on June 15, 2021.

[https://aec.army.mil/application/files/4714/9513/7494/Emerging\\_Contaminants\\_Program\\_Tutorial.pdf](https://aec.army.mil/application/files/4714/9513/7494/Emerging_Contaminants_Program_Tutorial.pdf)

Department of Navy. 2018. Environmental Restoration Program Manual.

Sellers, K., Nelson, D. and Weinberg, N., 2019. Emerging Contaminants: Anticipating Developments: Anticipating Developments. Taylor & Francis.