



ITRC PROJECT PROPOSAL:

Pharmaceuticals and Personal Care Products in Surface and Groundwater

Proposal Contact:

Iowa – POC Proposal Leader

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Call for Proposals Topical Area

The topical area addressed in this proposal is pharmaceuticals and personal care products (PPCPs), which is listed in the ITRC 2010 Request for Proposals.

Problem Statement (why is this project necessary and relevant to ITRC's purpose & mission¹?)

PPCPs in the environment have been identified by ITRC as an emerging issue. There is uncertainty in how they move in the environment and how they affect human and environmental receptors. Recent studies have demonstrated the widespread occurrence of PPCPs in the Nation's surface and groundwater resources as well as in finished drinking water, albeit at very low concentrations (nanogram per liter range). Heightened public awareness of this issue has resulted in pressure on federal and state agencies to develop strategies to control the release of these compounds into the environment, particularly to surface and groundwater resources. At present, there is no information resource available on which to base strategies to address PPCPs in surface and groundwater. This proposal would collect and evaluate existing information and collaborate with diverse professionals with experience in innovative wastewater technology, hydrogeology, agricultural engineering, chemistry, and environmental scientists to compile the resources needed to develop effective prevention and remediation strategies to address PPCPs in the environment.

This proposal is relevant to the ITRC mission because it addresses the environmental challenge of emerging contaminants from the ubiquitous use of PPCPs and readies ITRC resources to develop innovative solutions to address this challenge. For many of these emerging contaminants, risks are unknown and there are no drinking water standards.

Proposed Scope to Address Problem (what is the approach for this project?)

The issues to be explored in this proposal include: identification of known and suspected sources of PPCPs; existing data collection and evaluation efforts; fate and transport of PPCPs in the environment; compiling existing toxicological and risk assessment information and identification of data gaps in these areas; evaluate available prevention strategies for their potential to mitigate releases of PPCPs to the environment; evaluation of available remedial technologies for surface and groundwaters; and identification of emerging remedial technologies.

One of the challenges presented by PPCPs as an emerging issue is the large volume of disparate information that has not yet been effectively distilled into more useable forms for decision makers and

¹ **ITRC Purpose:** To advance innovative environmental decision making
ITRC Mission: Develop information resources and help break down barriers to the acceptance and use of technically sound innovative solutions to environmental challenges through an active network of diverse professionals.

organized in such a way as to facilitate efficient retrieval of the useful information. This project will work toward a goal of creating a user-friendly system of information that encompasses the various issues that surround PPCPs (sources, fate and transport, risk assessment, and mitigation) and adds value by putting the information in a context that is relevant to the management of PPCPs in the environment. For example, this project will examine the issues of occurrence, fate, and transport through a lens that allows decision makers to evaluate the relative importance of the various compounds for their local issues (source strength). The evaluation of source strength for PPCPs will result in a more targeted identification of the priority compounds and the priority issues for the individual compounds. Similarly, the lack of risk criteria also hampers the ability of the regulatory community and industry to respond effectively to the need for remediation and treatment technologies. Compilation of available toxicological data for this project will further the ability of regulators to develop potential risk criteria for PPCP compounds. Next, risk assessment information will be compiled and analyzed with respect to information gaps and needs. Prevention strategies and remediation technologies will be identified and summarized with respect to their ability to mitigate release of PPCPs into the environment, or remediate PPCPs in surface and groundwaters. Emerging technologies will also be reviewed for their potential to prevent or remediate PPCPs. As with the risk assessment, data gaps in knowledge will be identified and prioritized.

This project will develop a comprehensive review of topics surrounding the emerging issue of PPCPs in the environment and thus will provide a solid foundation for communicating effective remediation and prevention strategies. ITRC is well positioned to be successful with this project as the creation of a technical/regulatory guidance document and dissemination of the information is a central function of the ITRC.

Targeted Users (who will use products generated by this project?)

Because PPCPs are an emerging issue, and risk criteria have not been adopted, the primary users for this project would be the drinking and wastewater regulatory program areas in federal, state and local agencies that are tasked with setting proposed standards or limits for PPCPs in finished drinking water or final effluent discharges and biosolids. Other users would include wastewater recyclers, wastewater treatment plant operators, product manufacturers, consumers, analytical laboratory personnel, and environmental justice groups. Resources that would be developed by this project may also be applicable in the future to cleanup programs that address PPCPs in surface and groundwater.

This project would also address sources of pharmaceuticals from the livestock industry; therefore the products could also be used by program staff managing livestock siting and waste disposal decisions. Academic institutions and other research entities would use the information to set research priorities and address knowledge gaps.

In ITRC's State Engagement 2008 survey, states recognized this important issue by ranking it 3rd as an emerging issue that they are most concerned about, behind only alternative energy and climate change. Minnesota, New Hampshire and California identified PPCPs as a priority issue for their states, while Colorado, Iowa, Vermont, Massachusetts, Oregon, Florida, Illinois, and Michigan identified PPCPs as an emerging issue. In general, the states reported a need for information regarding the general ecological impacts from PPCPs and better scientific information for the regulation, remediation and mitigation of impacts for PPCPs.

Summary of Deliverables (primary project product(s))

To address the emerging issue of PPCPs in surface and groundwaters, three deliverables are proposed, including an issue overview document, a technical and regulatory guidance document and online training tool based on the technical and regulatory guidance document.

The first deliverable would be an Issue Overview Document that would provide an overview of the current research and knowledge regarding the issue of PPCPs in the environment. The overview document would compile and evaluate existing information on potential sources of PPCPs, discuss evaluation of those sources including fate and transport of PPCPs in the environment, summarize knowledge about distribution in the environment (surface and groundwater, sediments, and biosolids), and summarize available toxicological information to identify data gaps for risk assessment. This overview

document would be broad in nature and include sources such as agriculture and wastewater (septic tanks, wastewater, reclaimed wastewater, and combined and sanitary sewer overflows). This would be a highly valuable resource in that it would provide quantitative information. The work would focus on the mass flow of PPCPs into the environment as a means to identify and prioritize potential prevention strategies. In addition to human health concerns that are currently being addressed by multiple entities including the Board on Environmental Studies and Toxicology at the National Academies, it will place a needed focus on the ecological impacts from PPCPs.

This overview document is proposed to be completed as a stand-alone and published document. Because PPCPs in the environment is an emerging issue, a large amount of information would need to be compiled in an Overview document to provide a background for evaluating potential remedial technologies that would otherwise make a combined background and technical regulatory guidance document too unwieldy. In addition, publishing an initial overview document would be more timely and valuable to the identified product users. The Overview document is proposed to undergo formal ITRC review and become a published ITRC document.

The second deliverable would be a Technical and Regulatory Guidance document that would evaluate existing remedial technologies and their application to address PPCPs in surface and groundwater, and discuss emerging technologies and their potential as effective remedial technologies. Other important topics for the document will include identifying classes of PPCP compounds that behave similarly, indicator compounds, and secondary compounds resulting from breakdown of PPCPs. The document will review sampling and test methods for PPCPs, provide guidance for how to distinguish data of good and poor quality, information on how to develop a PPCP source inventory, and summarize current and potential treatment systems, as well as their costs, benefits and limitations. The guidance document will discuss information gaps and deliver suggestions for moving forward in the future.

The third deliverable would be Internet-Based Training based upon the technical and regulatory guidance document. The internet training will provide outreach on the guidance document and help to distill a very large and complex topic into manageable components for training.

Impact (how will this project result in more effective environmental decision making?)

This proposal aims to provide an initial overview document that reviews the most current literature and information regarding the identity and relative strength of sources of PPCP pollution, their fate and transport and pathways of delivery to the environment, and a compilation of available risk assessment data. Previous white papers and reviews of the issue have not taken such a comprehensive and broad perspective on the issue. For example, information on the occurrence of PPCPs in wastewater have focused on the application of biosolids to the landscape or delivery from effluent under normal conditions, but have not examined issues involved with sewer overflows, wastewater by-passes, reclaimed water or septic system contributions. This project aims to build on existing sources, but will go significantly beyond what has previously been compiled and will be a valuable resource as public water suppliers and state/federal environmental agencies work to address PPCPs in the environment.

The technical regulatory guidance document will provide an evaluation of the cost and effectiveness of existing remedial technologies and an evaluation of the potential effectiveness of emerging remedial technologies. Regulators will be provided with a clearinghouse of information regarding PPCPs that will cover the identification and evaluation of potential PPCP sources, fate and transport models, types of compounds and their risks, appropriate sampling techniques and test methods, mitigation measures, and efficient treatments.

Project Schedule

Target dates for the overview document, technical/regulatory guidance document and internet training.

2010

Form Team – identify leaders, state members, federal agencies, industrial partners, academic researchers and community stakeholders; evaluate individual skill sets.

Gather and review available data

Refine project scope and goals; form subteams; assign deliverables and schedules

Prepare Overview document outline

2011

Prepare draft of Overview document in 1st half of 2011

Release Overview document for review

Finalize Overview document

Release Overview document for review

Develop Technical/Regulatory guidance document outline

Begin to draft Technical/regulatory guidance document in 2nd half of 2011

2012

Finalize Technical/Regulatory guidance document in 1st half of 2012

Release Technical/Regulatory guidance document for review

Design and Prepare Internet Training in the 2nd half of 2012

Dry run of Internet training

Release final Technical/Regulatory guidance document for concurrence

2013 - 2015

Hold Internet trainings

Implement outreach

Proposed Personnel

Potential Team Membership/Needs

Proposed Team Leader: Mary P. Skopec Ph.D., Iowa Department of Natural Resources

Dr. Skopec holds the position of senior research scientist in the Watershed Monitoring and Assessment Section of the Iowa Department of Natural Resources. For the past ten years, Dr. Skopec has coordinated the monitoring of Iowa's surface and groundwater resources and worked closely with the regulatory programs in the Department to help interpret the results of the monitoring program to help inform these programs of emerging issues in surface and groundwater quality protection and guide potential responses to these issues (including the drinking water, wastewater, nonpoint source, and water quality standards programs).

Dr. Skopec holds an interdisciplinary Ph.D. from the University of Iowa with an emphasis in Environmental Science. In collaboration with the USGS, she worked to have Iowa become one of the first states to conduct systematic monitoring of surface waters to determine the presence of PPCPs. This work has provided her with an understanding of PPCPs and their potential threat to humans and the environment. Dr. Skopec is also member of the National Water Quality Monitoring Council and has previous experience leading technical work groups along with the skills needed to lead the proposed ITRC PPCP Team.

Co-leaders for the project would be identified during team development. The following states have expressed interest in team membership. Individuals have been part of the proposal development group and the reasons for participation are listed below.

- Iowa, Mary Skopec (see information above)
 - Iowa has expressed concern about the presence of PPCPs in drinking water and the need for technical guidance for treatment options.
- New York
- Massachusetts, David Noonan
 - Massachusetts wanted a better understanding of antibiotics in the environment.
- Oklahoma, Jim Shiraz

- Oklahoma expressed concern about the potential for livestock sources of PPCPs to contaminate drinking water supplies.
- California, Nicole Sotak
 - California noted a lack of information on the impact of PPCPs on human and environmental receptors. California also had interest in the topic due to potential impacts on groundwater from recycling of water or groundwater recharge projects.
- Oregon, Mavis Kent (proposal group), Kevin Masterson (proposed team member)
 - Oregon noted a need for a scientific basis for regulating wastewater discharges or soil remediation efforts.

Other organizations that have expressed interest in participating as team members:

- United States Geological Survey
- Arizona State University, Dr. Rolf Halden
- Product Stewardship Institute, Inc., Sierra Fletcher

Skill mix of Team members required:

- Environmental Engineering
- Toxicology and Risk Assessment
- Hydrogeology
- Environmental Science
- Chemistry
- Public Health

Sectors of Team members required:

- State officials from environmental regulatory agencies
- Academic members with research expertise in PPCPs
- Industry members with knowledge of remediation technologies
- Federal officials from environmental protection and regulatory agencies
- Non-profit members with expertise in community information and outreach
- Analytical laboratories

Proposed In-Kind/Direct Project Funding

No additional funding resources have been identified at this time. The proposal group will identify any potential resource to ITRC Director Anna Willett.

Related Work:

The project meshes well with other activities of the proposing team. For example, Arizona State University houses a nationwide repository of biosolids samples collected over the past two decades. This resource represents a snapshot of the chemistry and a time course of PPCP mass contained in land-applied municipal sludge. Also available are a comprehensive collection of literature compiled for a briefing of the Board on Environmental Studies and Toxicology at the National Academies, computer models for predicting the fate of PPCPs during conventional wastewater treatment, and a database of environmental threshold concentrations for susceptible organisms that can serve as ecological indicators to inform risk assessment analyses.