Environment and Natural Resources Trust Fund
2010 Request for Proposals (RFP)

LCCMR ID: 014-A2

Project Title:

New Risk Assessments for Endocrine Disruptors and Pharmaceuticals.

LCCMR 2010 Funding Priority:

A. Water Resources

Total Project Budget: $ $250,000

Proposed Project Time Period for the Funding Requested: 2 years, 2010 - 2012

Other Non-State Funds: $ $0

Summary:

Evaluation and comparison of alternative risk assessment methods for assessing potential human health risks from exposure to low levels of pharmaceuticals and hormonally-active contaminants in Minnesota drinking water sources.

Name: Helen Goeden

Sponsoring Organization: MN Department of Health

Address: 625 Robert St N
St. Paul MN 55164

Telephone Number: (651) 201-4904

Email: helen.goeden@state.mn.us

Fax: (651) 201-4606

Web Address: http://www.health.state.mn.us/divs/eh/

Location:

Region: Statewide

County Name: Statewide

City / Township:

_____ Knowledge Base _____ Broad App. _____ Innovation

_____ Leverage _____ Outcomes

_____ Partnerships _____ Urgency _____ TOTAL

MAIN PROPOSAL

I. PROJECT STATEMENT

The U.S. Geological Survey has found pharmaceuticals, such as acetaminophen, and chemicals that disrupt the endocrine system (e.g., estrogenic chemicals), such as triclosan and nonylphenol, in certain Minnesota drinking water sources. Policy makers and the public have expressed concern about potential exposure to and health risks from these chemicals. Currently there is no consensus among scientists and regulators on how to assess potential risks from these chemicals. These chemicals typically lack data regarding life stage sensitivity (e.g., infants) or other susceptible populations, and harm from long-term exposures at low levels. This lack of available data is problematic for using current standard risk assessment methods. Alternative risk assessment methods must take into account the pharmacological and endocrine effects of these chemicals in order to understand the potential for harm from exposure. Currently, MDH has not given advice on human health concern for endocrine disruptors and pharmaceuticals in drinking water and does not have staff available to conduct this work.

MDH proposes contracting with risk assessment experts to identify and use alternative methods for assessing risks from exposures to pharmaceuticals and hormonally-active chemicals. The contractors will compare different methods and recommend the best approaches for the state to use in the future. New methods must be compatible with current state risk assessments that address early life susceptibility to chemicals and evaluate a wide range of health effects. The contractors will use the recommended methods to assess risks from at least four substances that are found in Minnesota drinking water sources. Because of the lack of consensus on risk methods for these chemicals, MDH will arrange for a critical review of the results by peer scientists. MDH will also seek multi-state input on using the recommended methods. In addition, MDH will travel to professional meetings held with federal and state regulators to present and discuss the results. MDH staff will be trained to use the methods, critically evaluate the results, and appropriately guide regulators in using the results.

II. DESCRIPTION OF PROJECT RESULTS

Result 1: Identify potential alternative methods and tools for risk evaluation
Budget: $ 135,000

Contracted toxicology and risk assessment experts will identify, describe, and critique at least four methods for evaluating risks of pharmaceuticals and hormonally-active chemicals. MDH will require that the methods must: 1) consider the biological activity of a chemical and 2) be usable when there are minimal toxicity data. Contractors will also make recommendations on the optimal methods or tools to evaluate life stage sensitivity, susceptible populations (e.g., drug allergies), uncertainties and gaps in the available data, and health risks from mixtures of chemicals. At a minimum, the following methods will be evaluated: 1) the threshold of toxicological concern; 2) the margin of exposure; 3) use of an indicator with similar biological activity; and 4) computational models such as ToxCast™. Ideally, the methods would generate a health-protective water concentration (e.g., no adverse health effects are anticipated from long-term consumption of 3 parts per billion in water). The contractors will prepare a written report of the evaluation.

Result 2: Testing and comparing selected methods on four water contaminants
Budget: $ 85,000

Contracted toxicology and risk assessment experts will test the recommended methods (from Result 1) on at least four pharmaceuticals or hormonally active chemicals that have been detected in Minnesota drinking water sources. Chemicals will be selected in consultation with MDH. Staff will ensure that chemicals with a variety of biological activities and toxicity data will be tested. When possible, each of the four chemicals will be evaluated by each of the four or more methods. The results will be a variety of drinking water values (e.g., 3 parts per billion of chemical in water). The contractor will present, in a written report, a critique of which methods are optimal for types of chemicals, various health endpoints, data sets, life stages, health conditions, or other considerations.

Result 3: Communication and critique of results and recommendations
Budget: $ 30,000

Contracted planners/communicators will facilitate the peer review and plan and carry out communication of the results and recommendations. The expert peer review will be conducted with invited scientists from other states and academic institutions. In addition, MDH will host a seminar and training for Minnesota risk assessors, regulators, and the public. The results of this work (e.g., reports, seminar proceedings, peer review) will be communicated on a web page and through email distribution lists. Information will be conveyed to other states and federal agencies in presentations at two professional meetings. The planner will submit a written report of the workshop, the critique by peer scientists, and summaries of meetings.

Deliverable	Completion Date
1. Report on alternative methods for evaluating risks from pharmaceuticals and hormonally-active chemicals with limited toxicity data.	June 2011
2. Report on results of assessing risks and comparison of methods from an array of health-based risks.	December 2011
3. Communication of results and recommendations – web pages, workshop, critique by peer scientists, and report on communication.	June 2012

III. PROJECT STRATEGY

A. Project Team/Partners
The Minnesota Department of Health (MDH) will use a competitive process to contract with non-governmental entities such as a risk assessment science and engineering firm, risk assessors from academic institutions, and a communications specialist. Web development and writing will be completed through a part-time temporary hire through MDH.

B. Timeline Requirements
All work will be completed by the end of the two year project period (i.e., June 2012) although papers may be published after that period.

C. Long-Term Strategy
The results of this project will be used to advance the scientific and policy discussion regarding risk assessment methods for chemicals with insufficient data and may also be used for the evaluation of potential human health risks for future emerging contaminants.

Project Budget

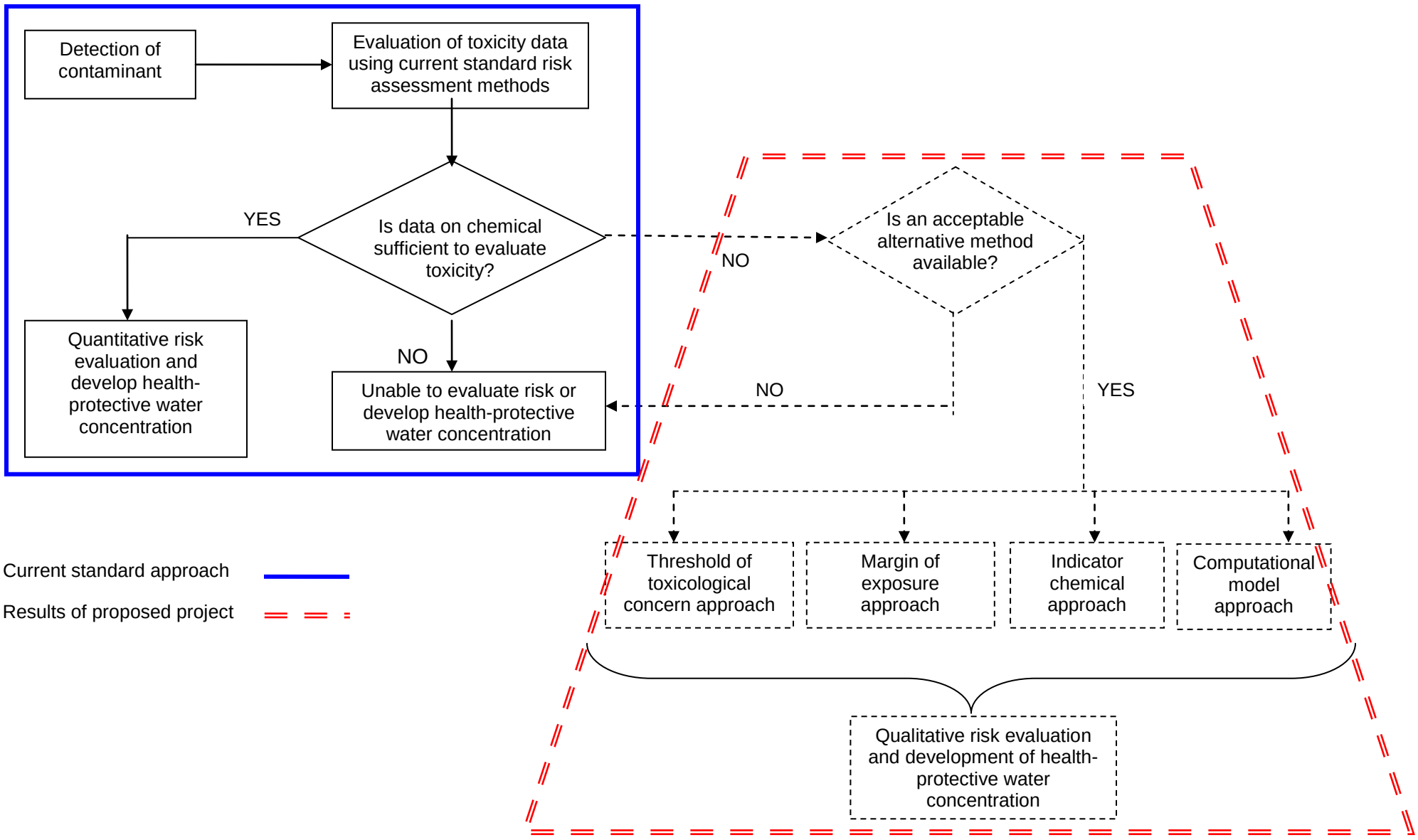
IV. TOTAL PROJECT REQUEST BUDGET (*2* years)

BUDGET ITEM	AMOUNT
Personnel:	$ 14,000
0.2 FTE web page design/web writer; MDH temporary employee	14,000
Contracts:	$ 231,500
Risk Assessment method review and development of guidance, Results 1 and 2; September 2010 through December 2011; toxicologist, risk assessor, project manager, and technical writer. Personnel costs range from $100 to 200 per hour; estimated total hours 1,200.	216,000
Meeting planning for multiple meetings and results/recommendations communication costs, Result 3, January through June 2011. Meeting planner and facilitation. Estimated average $100/hr x 80 hours	8,000
Peer scientist reviews, Result 3. Honoraria and travel of $2,500 for three scientists traveling to Minnesota in March 2011	7,500
Equipment/Tools/Supplies: software licenses for web work, computer models	$ 500
Travel: travel out-of-state to Federal-State Toxicology and Risk Assessment Committee in September 2011 and Society of Toxicology March 2011	$ 4,000
Additional Budget Items:	$ -
TOTAL PROJECT BUDGET REQUEST TO LCCMR	$ 250,000

V. OTHER FUNDS

SOURCE OF FUNDS	AMOUNT	Status
Other Non-State $ Being Applied to Project During Project Period:	$ -	none
Other State $ Being Applied to Project During Project Period:	$ -	none
In-kind Services During Project Period: Project administration by MDH technical and administrative staff (including MDH project manager, supervisor, and managers from Environmental Health Division, and staff and managers from MDH Financial Management Division. Estimated 1 FTE total over the two-year period (average of 0.1 FTE per person per year)	$ 104,000	
Remaining $ from Current Trust Fund Appropriation (if applicable):		none
Funding History: none	$ -	none

Illustration - Potential Impact of Proposed Project



Project Manager:

Helen Goeden, Ph.D.
Environmental Toxicologist
Health Risk Assessment
Minnesota Department of Health

Academic Training

1985 Ph.D., Environmental Health and Toxicology, University of Cincinnati Medical College, Cincinnati, Ohio
1980 B.S., Biology, minor in Chemistry, College of St. Scholastica, Duluth, Minnesota

Employment and Research Experience

12/2001 - present Research Scientist 3 - Minnesota Department of Health
Toxicologist and health risk researcher for the Health Risk Assessment Unit. Currently serving as lead toxicologist for the Health Risk Limits for Groundwater rule revision. Responsibilities also include: development of state-wide health-based criteria for groundwater; development and integration of risk assessment methods and policies that are protective of sensitive or highly exposed populations (e.g., infants); and case-by-case health risk assessments or research projects specific to emerging environmental health threats (e.g., perfluorochemicals).

10/1992 - 12/2001 Research Scientist 3 - Minnesota Pollution Control Agency
Toxicologist and risk assessor for the remediation and waste programs. Responsibilities included: development and implementation of multi-media human health risk assessment methodology; reviewing and evaluating scientific data on toxicity; and coordinating health risk assessment activities as well as acting as liaison with interagency programs (e.g., MDH, MDA).

1997 - Co-lecturer for Health Risk Evaluation Course, University of Minnesota.

12/1987 - 10/1992 Specialist - University of California at Berkeley

12/1986 - 10/1992 Toxicologist/Manager - Health Risk Associate, Inc.

9/1985 - 11/1986 Post-doctoral fellow - University of Calgary, Dept of Pharmacology

1/1984 - 5/1985 Research Assistant - University of Cincinnati

Professional Society Affiliations

Society of Toxicology, since 1986. Member of National Risk Assessment Specialty Section. Past Regional Chapter President
Society of Risk Analysis, since 1986. Founding member of the National Dose-Response Specialty Section.

Organization Description:

In recent years, the Minnesota Department of Health (MDH) has been active in conducting research in the area of evolving risk assessment methodology and emerging contaminants (e.g., perfluorochemicals). The MDH is able to both implement analysis of alternative approaches for developing human health-based guidance and develop health protection policy from the results of the analysis.