RUTGERS
NEWARK

Department of Biological Sciences
Faculty of Arts and Sciences-Newark
Rutgers the State University of New Jersey
Boyden Hall
195 University Avenue
Newark, NJ 07102-1814

www.rutgers.edu
newarkbiosci.rutgers.edu

973-353-5387
Fax: 973-353-5518

jweis@andromeda.rutgers.edu

Commissioner Bob Martin
NJ Dept. of Environmental Protection
Trenton, NJ

Sept. 20, 2012

Dear Commissioner Martin,

It is my pleasure to convey to you a report on Contaminants of Emerging Concern that has been approved by the Science Advisory Board. This report was written by a sub-committee of the Board, chaired by John Dyksen, with significant input from John Gannon. It was my great pleasure to be a part of this subcommittee.

I hope there will be a briefing for you scheduled in the near future for this report. It provides an excellent framework for DEP to approach this difficult problem.

Sincerely,

Judith S. Weis, Ph.D.
Chair, SAB

Response to Charge Question on

ISSUE: Contaminants of Emerging Concern

QUESTION: What are the Contaminants (surface water, ground water, air, biota, wastewater, & sediment) of emerging concern, and what technical (e.g., monitoring, research) steps should DEP take to understand and manage them?

Summary Report
of the NJDEP Science Advisory Board

Dr. Judith Weis, Ph.D. (chair)
Clinton J. Andrews, Ph.D., P.E.
John E. Dyksen, M.S., P.E.
Raymond A. Ferrara, Ph.D.
John T. Gannon, Ph.D.
Robert J. Laumbach, M.D., MPH
Peter B. Lederman, Ph.D., P.E.
Paul J. Lioy, Ph.D.
Robert J. Lippencott, Ph.D.
Tavit O. Najarian, Sc. D.
Nancy C. Rothman, Ph.D.
Anthony J. Broccoli, Ph.D.
Mark G. Robson, Ph.D.
David A. Vaccari, Ph.D., P.E.

September 2012

The following report has been issued by the Science Advisory Board to the Commission or the New Jersey Department of Environmental Protection:

Response to the Charge Question: What are the Contaminants (surface water, ground water, air, biota, wastewater, & sediment) of emerging concern, and what technical (e.g., monitoring, research) steps should DEP take to understand and manage them?

This report was prepared by the following members of the Science Advisory Board:

John Dyksen - Chair
Clinton Andrews
John Gannon
Jonathan Husch
Robert Laumbach
Peter Lederman
Paul Lioy
Mark Robson
Nancy Rothman
Judith Weis

Final Report
of the
Contaminants of Emerging Concern Work Group
of the
New Jersey Department of Environmental Protection
Science Advisory Board

Issue

Numerous chemicals, some of which may be a potential risk to human or environmental health, are used every day in New Jersey (NJ) for industrial, commercial and household purposes. Contaminants of Emerging Concern (CEC) are those that present a concern for both hazard and exposure. A number of these chemicals may find their way into the State's wastewater treatment facilities, receiving waters, aquifers and drinking water treatment facilities and other chemicals may be released to air or deposited in soils. CEC have raised concern around the world, as once released, these products pose a potential threat to biota and the environment. To address this issue specifically in New Jersey, the NJDEP Science Advisory Board (SAB) formed the CEC work group which was asked to investigate this issue. Addressing the concerns about these contaminants has been an ongoing challenge to regulators and utilities because of the vast number of compounds, the rapid advances in analytical techniques resulting in very low detection limits, the relative scarcity of information regarding potential human and ecosystem health effects as well as new uses and applications of new or existing chemicals which may present new potential exposure routes impacting humans and other biota as well as the quality of our environment.

Much research has been conducted to evaluate the impact of CECs on the aquatic environment[1-12], but much less research has been conducted on the impact of CECs on human health.[13-22] More research now is being conducted on the fate and transport of CECs in the environment and in water and wastewater treatment processes.[23]

To address the issue stated above and after much discussion, the CEC work group decided the best approach would be to develop a framework or methodology that can be used by NJDEP to identify and prioritize CECs particularly as they relate to NJ. This report provides a description of the proposed framework and is accompanied by a workbook (Appendix A) that was provided to the SAB at its June 2012 meeting. This workbook provides more

detailed information about the framework and the methodology proposed to conduct a preliminary hazard and exposure assessment.

Overall Framework

The objective of the proposed framework is to provide a NJ-specific methodology for assessing the hazard and exposure potential of chemicals found in the NJ environment or biota and prioritizing them for regulatory action based on risk assessment. The proposed CEC Prioritization Framework provides NJDEP with a robust, transparent, and science-based methodology for managing CECs in NJ. This framework can be used for any compound that may arise as a potential concern in NJ. In developing this framework, the work group reviewed several documents from both federal and state agencies regarding the assessment and prioritization of CECs.[24-31]

The overall framework includes 4 tiers:

> **Tier 1 - Initial Screen**: Determine whether the compound is a potential CEC in NJ. If so, the compound would be further evaluated under Tier 2.
>
> **Tier 2 - Preliminary Hazard & Exposure Assessment**: Characterize the compound based on empirical or estimated hazard and exposure information to develop a prioritization for conducting risk assessments. Based on a scoring process, it would be determined whether a compound would undergo a risk assessment under Tier 3 or be placed on a "waiting list" for future assessment.
>
> **Tier 3 - Risk Assessment**: Conduct both human and ecological risk assessments to determine whether a CEC candidate is a significant risk that merits consideration on the NJ CEC prioritization list. If a significant risk is determined, a risk management plan would be developed under Tier 4.
>
> **Tier 4 - Risk Management**: Develop recommendations for mitigating risk of chemicals identified as high risk concerns.

Each tier is described in the following paragraphs and further explained in Appendix A.

Tier 1 - Initial Screen

The initial screen involves asking three main questions about a compound to determine if, in fact, it is a potential CEC that could have an impact specifically in NJ:

- What is the nature of the government agency or stakeholder concern – where is the concern for the compound originating – monitoring data, media, growing usage, etc.?
- What type of contaminant category does the compound fall into – pharmaceutical, nanoparticle, pesticide, radionuclide, etc.?
- For what reasons could it be of concern in NJ – new chemical, new source, etc.?

Based on the information generated from these questions, NJDEP would determine whether the compound is a potential CEC in NJ that should be further investigated under Tier 2.

Tier 2 - Preliminary Hazard & Exposure Assessment

The objective of the Tier 2 Assessment is to categorize the compound based on available hazard and exposure information to determine whether the compound warrants a Risk Assessment under Tier 3. The first step under Tier 2 involves a determination of the availability of data to characterize the compound. The data used for the assessments should meet a data quality standard (criteria to be defined). In the absence of high quality empirical data, we would use estimates if applicable or hold a workshop of appropriate experts to identify what data are needed and how to obtain them. Once the data are available, we would characterize the compound with respect to hazard and exposure.

A hazard concern for human hazard will be based on the weight of evidence for the following endpoints:

- Acute Systemic Toxicity
- Carcinogen, Mutagen, Reproductive / Developmental Toxicity (including endocrine disruptors)
- Neurobehavioral Toxicity
- Repeated dose target organ toxicity
- Chemical Respiratory Sensitizer

A hazard concern for environmental hazard will be based on relevance of the human hazard endpoints and the weight of evidence for the following endpoints:

- Acute or Chronic Aquatic Toxicity
  - Fish toxicity
  - Crustacea toxicity
  - Algal toxicity
  - Terrestrial toxicity
- Consider any available data for sublethal -growth, reproduction, development, etc. responses or "real" ecological responses at the population or community level.

A potential CEC will be evaluated as an exposure concern based on the following criteria:

- Presence in NJ environmental media / biota at significant or steadily increasing concentrations or as significant biomarker measurements, and relative ranking of exposure based upon distributional estimates for the main routes of exposure (inhalation, dermal and ingestion) (ug/kg/day)
- Presence in food, children's toys, cosmetics/ personal care products, consumer product and relative ranking of exposure based upon distributional estimates for the main routes of exposure (inhalation, dermal and ingestion)

It is recommended that the hazard assessment be conducted using a platform called **METIS** (Metanomics Information System) developed by DuPont. **METIS** is a chemical informatics platform that provides a screening level view of potential environmental fate and effects, human health concerns, and societal perception concerns. This platform is built on open-source software that provides access to an aggregated database and estimation tool set. It pulls information from 1400+ publicly available databases which may contain, but are not limited to, physical chemical properties, hazard, and toxicological, environmental or regulatory information. Notably, the SAB recommends modification / customization of METIS to specifically address the needs of NJ DEP. The proposed hazard criteria are based on US EPA criteria.

It is recommended that the exposure assessment be conducted using a platform called **PRoTEGE** (Prioritization and Ranking of Toxic Exposures with GIS extension) that was developed by the Computational Chemodynamics Laboratory of the Environmental & Occupational Health Sciences Institute (EOHSI). **PRoTEGE** facilitates screening level exposure calculations at multiple tiers, utilizing available data including chemical production volumes, intrinsic properties, chemical usage, environmental concentrations, etc. The simplified

population-oriented approach of **PRoTEGE** provides estimates of exposures experienced by the US population, allowing calculations up to county-level resolution, and is intended to complement the more commonly used source-oriented approaches for screening level exposure characterization. The current **PRoTEGE** tool only includes evaluation of human exposure, but it can be easily adjusted to include eco-exposure.

Our recommendation includes merging the **METIS** and **PRoTEGE** systems, thereby creating a tiered computational system designed to support prioritization of CECs. The proposed system will be developed by systematically selecting, adapting, linking, testing, and eventually merging components from these two available and currently evolving state-of-the-art platforms for hazard and for exposure characterization and ranking. An eco-exposure module would be added to **PRoTEGE** and an algorithm would be written to accommodate the prioritization scoring for risk assessment described in the CEC framework. This merged system would provide NJ DEP with the leading state of the art system for rapidly evaluating the hazard and exposure potential of potential CECs. By doing so, this will place NJDEP in the forefront of state and national regulatory agencies for addressing CECs on a large scale.

Based on the output from these tools, the compound would be categorized either as a high concern (3), moderate concern (2), or low concern (1). A prioritization score would be calculated by multiplying the hazard rating by the exposure rating. Compounds with a high score would be further analyzed under Tier 3. Compounds with lower scores could be deferred for analyses (placed in "Parking Lot" in queue) at a later date or placed on a list of compounds that would be monitored and watched. Two U.S. EPA documents were reviewed in developing criteria for the preliminary assessments.[32,33]

Tier 3 - Risk Assessment

The Risk Assessment includes both Human (mammalian) & Ecological Risk Assessments and will determine whether or not a CEC candidate is a significant risk that merits consideration on the NJ CEC prioritization list. If, after the Risk Assessment, the compound is determined to be a high priority CEC, it would then be further evaluated under Tier 4. If it is not determined to be a high priority CEC, it would be placed on a list for future assessment or for monitoring in the event it rises to a high priority in the future.

Tier 4 - Risk Management

Risk Management of chemicals placed on the NJ CEC prioritization list will include recommended control or replacement options. It should be noted that the list needs to be manageable for NJ DEP with focus on mitigating risk of the most critical CECs for NJ. Under Risk Management, NJDEP would determine:

1. Who is responsible
2. What action is to be taken
3. Communication of the risk

Summary

The proposed framework will provide NJDEP with a robust, transparent, and science-based methodology for managing CECs in NJ. A critical element of the framework is the merging of the **METIS** and **PRoTEGE** systems. This work is necessary for the framework to be a useable tool.

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