Chemical Mixtures and Epidemiologic Fundamentals for Risk Assessment Applications

Workshop Leaders:
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Description:

Risk management options are increasingly being considered early in the risk assessment process to help scope the considerations and bound the inherent complexities related to potential exposures, risk and future clean-up decisions (including acceptable pollutant levels) related to contaminated sites. Exposure and health effects data in human populations can be used qualitatively and/or quantitatively in the different phases of risk assessments and can often help illuminate concerns regarding source or non-point source pollution or contaminated sites. The workshop will discuss the challenges in interpreting and using these types of information and provide instruction on identifying and addressing challenges and limitations related to human data. This workshop will discuss the basic information on human health risk assessments and highlight the potential uses and challenges with integrating epidemiological data that may be integral to some assessments, including those assessments addressing health risks posed by exposures to chemical mixtures.

Contaminated sites can often have various chemical and non-chemical stressors that should be evaluated for protection of human health and the environment. While the dose-response quantification and derivation of reference values in human health assessments are often on single chemicals, many sites usually have several in combination. Thus, another focus of this training will be to introduce some methods and procedures to address chemical mixtures at a site. The information in this workshop will provide some background material on practical and methodological considerations that are be applicable to a broad array of contaminated sites in both Europe and the United States. The risk information developed presented in this workshop will also illustrate the types of data to be communicated to the public through risk communication.

The workshop will have 2 sessions.

The first part (Epidemiological Fundamentals) of the training will address the fundamental principles related to epidemiology, as well as practical methods and data requirements for establishing causality and integrating epidemiological data into risk assessments. Participants will be introduced to elements of epidemiologic study design and the interpretation of common measures of association. Discussions will focus on identifying strengths and limitations of different types of human data, evaluating causality and integrating epidemiological data into risk assessments

The second part (Chemical Mixtures and Risk Assessment) of the training will be divided into two sections. The first section will summarize the human health risk assessment paradigm, including key concepts in exposure assessment and dose response assessment with discussion of approaches for developing reference values for non-cancer effects and oral slope factors for carcinogens. Because contaminated sites often have many inorganic and organic chemicals that humans can be exposed to at the same time, the second session will include an overview of human health risk assessment methods that can be used to estimate health risks associated with chemical mixtures. Both component methods and whole mixture methods that can be used to evaluate the risk posed by such exposures will be introduced. The last part of the workshop will focus on a practical exercise on risk assessment considerations and quantification for a hypothetical site contaminated with chemical mixtures.

Workshop Goals:

1. Become a more intelligent consumer of epidemiological information
2. Gain an understanding of basic human health risk assessment, including the development of dose-response data
3. Gain an appreciation of chemical mixtures risk assessment methods

Session 1

Epidemiologic Fundamentals for Risk Assessment Application: Presenter Dr. Michael Wright

- Epidemiology Study Designs and Measures of Disease and Association
- Causality – Epidemiological and Statistical Inference
- Methodological Considerations (Explanations of observed Data)
    - Internal and External Validity (Confounding and other Types of Biases)
    - Exposure Assessment and Disease Clusters
- Effect Measure Modification

Session 2 Basic Principles of Human Health Risk Assessment and Chemical Mixtures Risk Assessment: Presenter Dr. Glenn Rice

- Risk Concepts
- Risk Assessment Paradigm Overview
    - Exposure Assessment
    - Dose-Response Assessment
    - Risk Characterization
- Chemical Mixtures Risk Assessment
    - Component Methods
    - Whole Mixture Methods

Case Study: Hypothetical site contaminated with arsenic and PCBs

Many former industrial sites in the US, Europe and Asia are contaminated with multiple contaminants including arsenic and polychlorinated biphenyls (PCBs). For this case, a hypothetical waste site with elevated levels of both contaminants will serve as an example. The example will address the use of arsenic and PCB soil concentration data to estimate exposures; the development of oral cancer slope factors for both chemicals; and the use of response addition to estimate cancer risks posed by such mixtures.

Chemical Mixtures and Epidemiology Workshop Agenda
Sunday, June 10, 2018
10:00 a.m. – 3:30 p.m.

10:00 – 10:05 a.m.	**Introduction/Workshop Goals**
10:05 – 10:40 a.m.	**Epidemiology Study Designs and Measures of Disease and Association**
10:40 – 10:55 a.m.	**Causality – Epidemiological and Statistical Inference**
10:55 – 11:05 a.m.	**Exposure Assessment & Disease Clusters**
11:05– 11:40 a.m.	**Methodological Considerations: Confounding and other Biases**
11:40– 11:50 a.m.	**Effect Measure Modification**
11:50 a.m. – 12:00 p.m.	**Questions**
12:00 – 1:00 p.m.	**Lunch Break**
1:00 – 1:45 p.m.	**Risk Assessment Essentials**
1:45 – 2:30 p.m.	**Chemical Mixtures Risk Assessment**
2:30– 2:45 p.m.	**Break**
2:45 – 3:15 p.m.	**Case Study**
3:15 – 3:30 p.m.	**Questions and Wrap-up**