

Workshop on Systematic Review

Date: March 9, 2015

Time: 9:00 am-12:30 pm

Organizing Committee: Food and Drug Administration, National Institute of Environmental Health Sciences, National Institutes of Health, Environmental Protection Agency and Johns Hopkins University

Location:

Center for Food Safety and Applied Nutrition-Wiley Auditorium
5100 Paint Branch Parkway
College Park, MD 20740-3835

Workshop Description “What is Systematic Review? An Introductory Course”:

Systematic review and related evidence-based approaches are beginning to be translated from healthcare to toxicology. They provide transparent, objective, and consistent tools to identify, select, appraise, and extract evidence across studies. Systematic review methodologies provide objectivity and transparency to the process of collecting and synthesizing scientific evidence in reaching conclusions on specific research questions. Procedures are explicitly defined in advance, in order to ensure that the exercise is transparent and can be replicated. This practice is also designed to minimize bias. Systematic review procedures are being adopted by other federal agencies, including EPA and NIEHS.

Studies included in a systematic review are screened for quality, so that the findings of a large number of studies can be combined.

A systematic review must have:

- Clear inclusion/exclusion criteria
- An explicit search strategy
- Systematic coding and analysis of included studies
- Meta-analysis (where possible)

This workshop will present a framework for systematic review and evidence integration for reaching hazard identification conclusions. General steps used for the systematic review include the following: 1) formulate problem and develop protocol, 2) search for and select studies for inclusion, 3) extract data from selected studies, 4) assess the quality or risk of bias of individual studies, 5) rate the confidence in the body of evidence, 6) translate the confidence ratings into levels of evidence, and 7) integrate the information from different evidence streams (human,

animal, and "other relevant data" including mechanistic or in vitro studies) to develop hazard identification conclusions.

Systematic review methods do not supplant the role of expert scientific judgment, public participation, or other existing processes used by federal agencies in the evaluation of environmental substances. Instead, the systematic review methods provide a great strategy for evidence-based decision making in terms of ensuring the collection of the most complete and reliable evidence to form the basis for decisions or conclusions. Knowledge of the quality and confidence in the evidence is essential to decision making.

Registration: Please select the following link to register for the workshop

<https://www.surveymonkey.com/r/GYGDBM9>

Remote Access Information:

<https://fda.webex.com/fda/onstage/g.php?d=748691663&t=a>

Event number: 748 691 663

Event password: 1234

For additional information regarding the course, please contact Marcy Wexler, marcy.wexler@fda.hhs.gov, 240-402-4856

Reasonable Accommodations:

The FDA provides reasonable accommodations for all individuals with disabilities who apply for training or developmental opportunities. If you need a reasonable accommodation for any part of the training application process please notify the training contact for this particular event.

Reasonable accommodation requests are granted on a case-by case basis. Should you need sign language interpretation to attend this event, please send the request to

Interpreting.Services@oc.fda.gov