



# HESI®

ILSI Health and Environmental Sciences Institute

HESI Bioaccumulation Project Committee

Workshop on:

*“Moving bioaccumulation assessments to the next level: progress made and challenges ahead”*

February 8 – 10, 2011

Crowne Plaza Alexandria

901 North Fairfax Street

Alexandria, VA

*FINAL AGENDA*

**Background:** Since it was formed in 2005, the HESI Bioaccumulation Project Committee has successfully advanced the science of bioaccumulation (‘B’) in several areas: developing *in vitro* methods as part of weight of evidence approaches to ‘B’ assessment; publishing peer reviewed papers on the state of ‘B’ science; advancing models to better screen organic chemicals for ‘B’; and funding research in basic fish physiology to better understand ADME processes. In addition, the HESI committee has collaborated with SETAC and others to sponsor workshops bringing together academia, industry and regulatory authorities to discuss and advance ‘B’ science.

**Goals:** The goal of this workshop is to highlight recent and ongoing research efforts, to demonstrate progress that has been made in the field, to identify key gaps in current ‘B’ knowledge, and to discuss obstacles that hinder implementation of the recent progress in ‘B’ science into the regulatory environment. Topics will include integration of modeled predictions with laboratory measurements, extrapolation from lab to field data, a review of ADME processes and determining method domain of applicability across chemicals and species, and abbreviated BCF studies. In addition to discussing research efforts, we are very interested in hearing about the potential incorporation of these methods into regulatory ‘B’ assessments and what is needed to best communicate the scientific advancements to the risk assessment community. The ultimate output of this workshop will provide guidance to the HESI ‘B’ Project Committee to further develop the research program and move the science of bioaccumulation forward.

**Audience:** We anticipate a global, balanced workshop, with ~65 key scientists and regulators from North America, Europe, Japan and Australia in attendance. The workshop will bring together industry, academia, government, and NGOs to discuss and address bioaccumulation issues.

**Structure:** This workshop is separated into five separate sessions, with most of the time dedicated to focussed breakout group discussions:

- **Session I** will consist of a series of plenary talks followed by discussion highlighting the work of the HESI Bioaccumulation Project Committee. This session will cover the research projects sponsored by HESI and other partners (such as CEFIC LRI, USEPA, and ECVAM). A poster reception will be held on the evening of the first day, providing an opportunity for more in-depth discussion and presentation of the committee work.
- **Session II** will highlight advanced methods in the field, providing a current “state of the science” discussion with critical analysis of strengths and weakness of each new approach. This session will complement Session I, but includes all recent advances and will allow for a “deep drill” discussion via targeted breakout groups focused on QSARs & modeling, *in vitro* methods, modified *in vivo* methods, and field data & models.
- **Session III** is dedicated to pushing things forward. This session will identify the new work that is needed in each of the key areas discussed in Session II in order to better utilize and advance new ‘B’ methodologies.
- **Session IV** will shift gears and discuss how various metrics used to assess ‘B’ potential discussed in the previous sessions can be used in a weight of evidence approach to arrive at assessment conclusions
- **Session V** will synthesize the workshop discussions and allow for general brainstorming related to the research and training that is needed to address challenges.

Tuesday, 08 February 2011

**SESSION I: INTRODUCTORY PLENARY (Washington Room)**

**Scope:** This session will provide brief updates on research projects sponsored by HESI and other partners. A poster reception will be held the evening of February 8th, providing an opportunity for more in-depth discussion and presentation of the committee work.

8:00 – 8:30	Continental breakfast	
8:30 – 8:45	Introductions	
8:45 – 9:00	Overview of the HESI project	<i>C. Cowan-Ellsberry</i>
9:00 – 9:20	QSAR development / Apparent $k_m$ modeling / Dietary efficiency modeling	<i>J. Arnot</i>
9:20 – 9:40	S9 Assay development	<i>K. Jobanning</i>
9:40 – 10:00	Bioavailability work & extrapolation model (S9 applicability)	<i>B. Escher/C. Cowan-Ellsberry</i>
10:00 – 10:20	Fish physiology	<i>L. Petersen</i>
10:20 – 10:35	Gut cell line	<i>K. Schirmer</i>
10:35 – 10:55	Hepatocytes	<i>X. Han</i>
10:55 – 11:10	BREAK	
11:10 – 11:30	Shortened <i>in vivo</i>	<i>D. Hala</i>
11:30 – 11:50	Benchmarking and passive dosing/sampling in fish BCF experiments	<i>M. McLachlan</i>
11:50 – 12:10	Lab-Field	<i>H. Selck</i>
12:10 – 12:30	Update on OECD 305 TG Revisions	<i>D. Merckel</i>
12:30 – 1:30	LUNCH ( <b>Kennedy Room</b> )	

**SESSION II: ADVANCED METHODS** (Chairs: *Sue Erhardt, Jean Domoradzki, Marlies Halder*)

**Scope:** This session will highlight new advances in the field, providing a current “state of the science” discussion, with critical analysis of strengths and weakness of each new approach (which will lead into the “data gaps” discussion in Session III)

1:30 – 2:00	State of the science for advanced methods	<i>S. Erhardt</i>
2:00 – 2:15	“Charge” to breakout groups and move to rooms	<i>J. Domoradzki</i>
2:15 – 2:30	BREAK (move to breakout rooms)	
2:30 – 4:30	Concurrent breakout sessions (4 groups)	
4:30 – 4:45	BREAK (move to plenary room)	
4:45 – 5:45	Report-outs & discussion (15 minutes for each group)	
6:30 – 8:00	Poster reception ( <b>Jefferson Room</b> )	

Wednesday, 09 February 2011

8:00 – 8:30 Continental Breakfast

**SESSION III: NEW WORK NEEDED** (Chairs: MaryJo Bernhard, John Nichols, Helmut Segner)

**Scope:** Session III will focus on prioritization of research needs based on various criteria (e.g., ease of completion, known or suspected contribution of assessment uncertainty, relevance for implementation in the regulatory assessment, etc) and identification of a step-wise research strategy.

8:30 – 9:30 Session “set up” J. Nichols

9:30 – 9:45 BREAK (move to breakout rooms)

9:45 – 12:00 Concurrent breakout sessions (4 groups)

12:00 – 1:00 LUNCH (**Kennedy Room**)

1:00 – 2:00 Report-outs & discussion (15 minutes for each group)

**SESSION IV: FORMING A WEIGHT OF EVIDENCE FOR BIOACCUMULATION** (Chairs: Mark Bonnell, Christina Cowan-Ellsberry, Marlies Halder)

**Scope:** This session will focus more on the current status, whereas a more in-depth discussion of what information / data is needed for regulatory acceptance of new methods might occur in Session V at the end of the meeting.

2:00 – 2:30 Plenary talk M. Bonnell (via phone)

2:30 – 2:45 BREAK (move to breakout rooms)

2:45 – 4:45 Concurrent breakout sessions (4 groups)

4:45 – 5:00 Wrap-up of Day 2

Thursday, 10 February 2010

8:00 – 8:30 Continental Breakfast

8:30 – 9:30 Report-outs & discussion from Session IV (15 minutes for each group)

9:30 – 9:45 Open discussion

9:45 – 10:00 BREAK

**SESSION V: ASSIMILATION/ GENERAL BRAINSTORM**

**Scope:** Bring together the various issues discussed in Sessions II, III, and IV; circle back to the key questions surrounding regulatory acceptance.

10:00 – 12:00 Facilitated discussion / small group dialog

12:00 – 12:30 Wrap-up

12:30 Adjourn (boxed lunch provided)