**Nano WG Meeting**

**July 27, 2011**

**Nano-SAR Presentations**

**Attendees**:

Elaine Freund, 3rd Mill

Nathan Baker, PNNL

Dennis Thomas, PNNL

Fred Klaessig, Pa BioNano

Jessica Adamick, NNN

Juli Klemm, NCI

Kaizhi Tang, I-A-I

Krzysztof Ptak, NCI

Kirk Kitchin, EPA

Liz Hahn-Dantona, NCI EVS

Mark Hoover, CDC

Stacey Harper, OSU

Amy Bednar, Army

Denis Fourches, UNC

**FDA Draft Guidance**

The FDA is seeking input regarding draft guidance on nanoparticles. Crafting a response had support via e-mail. There was a question of whether government organizations can respond. An alternative is to invite Carlos to meeting and provide informal feedback. Avoid interagency issues.

Ai: Nathan to do introductory e-mail

AI: Elaine to schedule Carlos on a call

**Presentation: Stacey Harper**

An EZ Metric for Defining the A in nanoSARs

Stacey Lynn Harper

The rapid rate of discovery and development in nanotechnology will undoubtedly increase the potential for both human and environmental exposures to novel nanomaterials. While numerous applications promise benefit to human health or the environment, the potential health and environmental risks associated with the unique properties of nanoscale materials are unknown and may lead to unintended health and safety consequences. The current gap in nanomaterial toxicological data dictates the need to develop rapid, relevant and efficient testing strategies to assess these emerging materials of concern prior to large-scale exposures. Stacey will present an alternative approach that utilizes a dynamic whole animal (*in vivo*) assay to reveal whether a nanomaterial is potentially toxic at multiple levels of biological organization (i.e. molecular, cellular, systems, organismal).  Early developmental life stages are often uniquely sensitive to environmental insult, due in part to the enormous changes in cellular differentiation, proliferation and migration required to form the required cell types, tissues and organs. Molecular signaling underlies all of these processes. Most toxic responses result from disruption of proper molecular signaling, thus, early developmental life stages are perhaps the ideal life stage to determine if chemicals or nanomaterials are toxic. Therefore, the embryonic zebrafish model was chosen to investigate nanomaterial biological activity and toxic potential.  Investigations using this model system can reveal subtle interactions so we have developed an ‘EZ’ (embryonic zebrafish) Metric for nanomaterial toxicity’ (EZ Metric) that takes into account the types and frequency of sublethal effects in addition to overt mortality.  The EZ Metric has been used to compare morbidity and mortality elicited from exposure to over 200 novel engineered nanomaterials using the Nanomaterial-Biological Interactions knowledgebase at Oregon State University.

Q. What was the rationale for selecting the 200 nanoparticles evaluated?

A. Gold was from strategic partnerships, industry partners in ONAMI who want to know relative impact of the particles they are producing. They want to know toxicity. They are lacking some of the characterization data that is needed for structure property relationships.

It will help if you can see trends in a material class, including negative data. Most materials do not generate a significant response.

Q. Do you compare profiles with known chemical toxicants?

A. Yes

Q. Age for micro injection?

A. Single cell stage. Hit at critical periods, the effect depends on time of exposure. We won’t say predictive of a human exposure. You can also go back and close window of exposure by putting the fish in fresh water and seeing if they can recover. You can also look at gene responses on this.

Q. This seems to be an Ames test on nano toxicity. Can others set this up or do they go to you?

A. There are a few other groups doing the assay. There are some variations, some take off chorion or not – so it is not necessarily comparable. ONAMI always does the same protocol. Since the value of the zebrafish data is from looking across large data sets, it is not the same as an AMES test.

**Presentation - Mark Hoover:**

C2 Nanoinformatics tools; [Mark D. Hoover](http://www.uml.edu/nano/nanoehs/Documents/Mark%20Hoover%20BioSketch-photo.pdf), Ph. D., CHP, CIH, NIOSH

This course will foster understanding and use of important tools and resources described in the *Nanoinformatics 2020 Roadmap* ([www.nanotechinformatics.org](http://www.nanotechinformatics.org)). Nanoinformatics is the science and practice of determining which information is relevant to the nanoscale science and engineering community, and then developing and implementing effective mechanisms for collecting, validating, storing, sharing, analyzing, modeling, and applying that information. Key national and international nanoinformatics leaders including Dr. Michelle Ostraat of the Nanomaterials Registry, Dr. Ilise Feitshans from the Geneva School of Diplomacy, and Dr. Michael Riediker of the University of Lausanne will assist with presentations and discussions. Examples of tools that will be covered include:

* guidance on safe handling of nanomaterials from [www.cdc.gov/niosh/topics/nanotech/](http://www.cdc.gov/niosh/topics/nanotech/) and [www.*Good*Nano*Guide*.org](http://www.GoodNanoGuide.org);
* nanomaterial characteristics and hazard information from the Nanomaterials Registry and from [www.nanoparticlelibrary.net](http://www.nanoparticlelibrary.net);
* computational resources for modeling and simulation in nanotechnology from resources such as the National Science Foundation’s [www.nanoHUB.org](http://www.nanoHUB.org), the National Cancer Institute’s <https://cabig.nci.nih.gov/tools/caNanoLab>, and the Nanomaterial-Biological Interactions Knowledgebase (<http://nbi.oregonstate.edu/>); and
* information on nanotechnology-related changes in the legal arena from [www.forecastingnanolaw.net](http://www.forecastingnanolaw.net).

The workshop is on the science of how you do things. Nanoinformatics is the topic Mark is speaking on.

He wants to address how to go into a workplace, capture work process and things being handled, particle size and concentration over time. Where do exposures occur, have you controlled to an appropriate level, do you have information for epidemiological studies of your workers? What are the characteristics they need to be concerned about?

Walked through Nanoinformatics 2010, plans for 2011 and the wires doc.