From: John Whalan
To: Ravi Subramaniam
Subject: Revised outline/schedule
Date: 01/26/2009 02:36 PM

Formaldehyde: Tox Review Outline

January 26, 2008

Responsible parties and draft due dates are in **Blue**. The first name is the lead for a section. Statuses of chapters and sections are in **Red**

1. INTRODUCTION – **Whalan** - **Draft complete**
2. PHYSICOCHEMICAL CHARACTERISTICS – **Thompson** - **Draft complete**
3. TOXICOKINETICS – **Thompson** - **Draft complete**
   - 3.1 Chemical Properties and Reactivity
   - 3.2 Absorption and Distribution (*add a few sentences linking to chapter 4*)
   - 3.3 Metabolism
   - 3.4 Excretion
   - 3.5 Pharmacokinetic Modeling
   - 3.6 References - **ORISE**
4. INHALATION DOSIMETRY MODELING – **Subramaniam** - **Draft complete**
   - 4.1 Differences in Airway Anatomy and Consequences for Dosimetry
   - 4.2 Modeling Formaldehyde Uptake in Nasal Passages
   - 4.3 Uncertainties in Formaldehyde Dosimetry Modeling
   - 4.4 Modeling DNA Protein Cross-Links (DPXs) Formed by Formaldehyde
   - 4.5 Prediction of Human DPX Concentrations in Conolly et al., (2000)
   - 4.6 Mode-of-Action Uncertainty in the Use of DPXs as a Dose Surrogate for Mutation
   - 4.7 References - **ORISE**
5. HAZARD CHARACTERIZATION AND MODE OF ACTION – **DeVoney (draft due 1-31-09)**
   - 5.1 Human Studies - **Bateson**
     - 5.1.1 Noncancer Health Effects
       - 5.1.1.1. Sensory irritation – **Vinikoor (draft due 1-24-09)**
       - 5.1.1.2. Effects on asthmatics –**Vinikoor (draft due 1-24-09)**
       - 5.1.1.3. Pulmonary Function – **Vinikoor (draft due 1-24-09)**
       - 5.1.1.4. Respiratory Tract Histopathology - **Bateson** - **Draft complete**
       - 5.1.1.5. Immunological - **Bateson** - **Draft complete**
       - 5.1.1.6. Neurological / Behavioral – **Bateson** - **Draft complete**
       - 5.1.1.7. Developmental and Reproductive - **Bateson, Euling** - **Draft complete**
     - 5.1.2 Carcinogenicity – **Bateson** - **Draft complete**
   - 5.2 Animal Studies - **DeVoney**
     - 5.2.2 Noncancer Health Effects
       - 5.2.1.1. Reflex Bradypnea - **DeVoney**
       - 5.2.1.2. Eye, Nose, Throat Irritation - **DeVoney**
       - 5.2.1.3. Respiratory Tract Pathology - **DeVoney**
       - 5.2.1.4. GI Tract Pathology - **DeVoney**
       - 5.2.1.5. Immunotoxicity - **DeVoney**

5.2.1.6. Neurological / Behavioral - **Raffaele**
5.2.1.7. Sensitization - **Backus**
5.2.1.8. Developmental and Reproductive – **Makris, Euling, Bateson**
5.2.3 Carcinogenicity - **DeVoney**
5.3 Genotoxicity – **Vulimiri (draft due 1-31-09)**
5.4 Toxicogenomics - **Thompson, Subramaniam, Euling (draft due 1-31-09)**
5.5 Synthesis and Evaluation of Major Noncancer Health Effects (2008 version) - **DeVoney**
5.5.1 Sensory Irritation - **DeVoney**
5.5.2 Pulmonary Function – **DeVoney**
5.5.3 Asthma and Atopy - **Backus**
5.5.4 Respiratory Tract Histopathology - **DeVoney**
5.5.5 Immunotoxicity – **Backus**
5.5.6 Neurological / Behavioral - **Raffaele**
5.5.7 Developmental and Reproductive – **Makris, Euling, Bateson**
5.6 Evaluation of Carcinogenicity – **DeVoney (draft due 1-9-09)**
5.6.1 NPC – **DeVoney, Subramaniam, Jinot, Vulimiri**
5.6.2 LHP – **DeVoney, Subramaniam, Jinot, Vulimiri**
5.6.3 GI – **DeVoney, Subramaniam, Vulimiri**
5.7 Susceptible Populations – **Backus**
6. DOSE-RESPONSE ANALYSIS – **Subramaniam (cancer) & Whalan (non-cancer) (draft due 2-28-09)**
7. Summary - **Subramaniam (cancer) & Whalan (non-cancer)(draft due 2-28-09)**
6.1 Quantitative Cancer Risk Assessment Based on the NCI Epidemiology Study – **Jinot** - **Draft complete**
6.2 Biologically Based Dose-Response Modeling Based on Laboratory Data – **Subramaniam** – **Draft complete, but needs minor modification**
6.3 Benchmark Dose Approaches to Rat Nasal Tumor Data - **Subramaniam** – **Draft complete**
6.4 Benchmark Dose Approaches for Other Rodent Cancer Data (i.e. Sofritti LHC and GI) - **Jinot**
6.5 Oral Reference Dose (RfD) – **Subramaniam** - **Draft complete**
6.6 Inhalation Reference Concentration (RfC) – **Farrar**, Hogan
6.7 References – **ORISE**
7. CHARACTERIZATION OF HAZARD AND DOSE-RESPONSE – **Subramaniam** (cancer) & **Whalan** (non-cancer) **(draft due 3-18-09)**
7.1 Summary of Human Hazard Potential – **Bateson**
7.1.1 Exposure – **Schaum**
7.1.2 Absorption, Metabolism, Distribution, and Excretion - **Thompson**
7.1.3 Noncancer Toxicity I Humans and Laboratory Animals - **Whalan**
7.1.4 Carcinogenicity in Humans and Laboratory Animals – **Subramaniam**
7.1.5 Mode-of-Action Information - **DeVoney**
7.1.6 Weight of Evidence Descriptor for Cancer Hazard - **Subramaniam**
7.2 Dose-Response Characterization – **Subramaniam**
7.2.1 Noncancer Toxicity (RfC/RfD) - **Whalan**
7.2.2 Cancer Risk Estimates - **Jinot**
7.3 References - **ORISE**

Toxicologist, ORD - NCEA - IRIS
Phone: 703-347-8639 FAX: 703-347-8689

US EPA, Mailcode 8601D
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Physical location & FedEx:
Two Potomac Yard, Suite N-7211
2733 S. Crystal Drive, Arlington, VA 22202