Susan P. Felter, Ph.D.

Education:

University of Cincinnati
Department of Environmental Health
Degree: Ph.D., Toxicology (Sept. 1994). Thesis: "Activation of the H-*ras* Oncogene in Liver Tumors of Male B6C3F1 Mice Induced by Drinking Water Disinfection By-Products"

Massachusetts Institute of Technology
Cambridge, MA
Degree: B.S., Biology (Feb. 1984)

Experience:

Procter and Gamble: 1997 to present
Mason Business Center; Cincinnati, OH 45040

Title: Research Fellow, Central Product Safety

Responsibilities:

- Lead internal Quantitative Safety Assessment Expert Team, which is responsible for integrating approaches and research led by teams on Cancer and Noncancer Safety Assessment, Exposure Assessment, and the application of the Threshold of Toxicologic Concern (TTC) method. Provide basic and advanced risk assessment training for new or transferred toxicologists
- Lead Cancer Risk Assessment and TTC Expert Teams, which are responsible for developing and making recommendations for global policies to support internal safety assessment methodologies and TTC applications and ensure a robust technical basis for safety decisions, as well as ensuring global regulatory compliance. Conduct mechanism-based cancer risk assessments to support global company needs.
- Provide technical support to Global Baby Care organization to ensure our safety assessment methods are robust and ensure safety for early life exposures.
- Responsible for managing technical issues for selected key raw materials and classes of compounds.

***TERA* (Toxicology Excellence for Risk Assessment): 1995 - 1997**
Cincinnati, OH 45223

U.S. Environmental Protection Agency: 1989 - 1995
Environmental Criteria and Assessment Office; Office of Research and Development
Cincinnati, OH 45268

Professional Activities and Societies

U.S. Environmental Protection Agency

- Science Advisory Board: October 2015- Present

National Center for Toxicological Research (NCTR); Food & Drug Administration

- Science Advisory Board: October 2014- 2018

World Health Organization (WHO)

- Selected expert for three-day workshop, co-hosted by EFSA and the WHO, to update the science underlying the Threshold of Toxicological Concern (TTC) concept. (December 2014)
- Temporary Advisor to Who for IPCS Task Group on Environmental Health Criteria for Thallium. Geneva, Switzerland. (December 1994)

Toxicology Forum

- Science Advisory Board: 2012 – 2016
- Program Planning Committee: 2012-2015; Finance Committee: 2015 - 2016

European Commission

- Invited scientific expert to analyze the status and prospects of alternative methods in the area of carcinogenicity to achieve full replacement of animal testing (2010-2011)

Society of Toxicology

- Full member since 1996
  * Secretary-Treasurer of the Risk Assessment Specialty Section of SOT (1997-1999)

Society for Risk Analysis

- Member 1995 - 2005
- Member of Ohio Chapter of SRA (1992-2003)
  * Councilor (1997-1999)

Selected Invited Presentations

October 2016: Human Relevance of Rodent Liver Tumors (Arlington, VA). Co-chair of Workshop sponsored by the Toxicology Forum.

September 2016: International Conference on Toxicity Testing Alternatives & Translational Toxicology (Hangzhou, China): Threshold of Toxicological Concern (TTC): History, Current Use and Future Opportunities

May 2016: FDA/SOT Colloquia (Washington DC): Emerging Toxicological Science Challenges in Food and Ingredient Safety: Safety Approaches in Young Children.

September 2015: Eurotox (Porto, Portugal). Chair of Session 47: Physiology of Infant Skin and Considerations for Quantitative Risk Assessment of Dermally Applied Substances; Speaker on topic of "Diapered Skin and Diaper Dermatitis: Implications for Risk Assessment." September 16.

July 2014: Toxicology Forum (Aspen, CO): Chaired session on Mouse Lung Tumors: Considerations for Risk Assessment

July 2013: NA Toxicology Forum (Aspen, CO). Chair of Session V: Consideration of Infants & Children in Quantitative Risk Assessment. July 10.

October 2012: PCPC Science Symposium (Washington, DC). Risk Assessment of Personal Care Products for Babies and Children. October 4.

May 2012: Thresholds of Toxicological Concern for Food Workshop (Beijing, China). Sponsored by ILSI Focal Point in China and the China National Centre for Food Safety Risk Assessment. Talk 1: The Tiered TTC Approach and Application to Trace Contaminants in Foods. Talk 2: In-Depth Evaluation of the Noncancer Tiers; Demonstration of the ToxTree Tool. May 24.

March 2012: PCPC Regulatory Science Symposium (Washington, DC). Risk Combined Exposure to Multiple Chemicals: Perspectives from a Personal Care Products Company. March 29.

February 2012: NA Toxicology Forum (Washington, DC). Chair of Session V: Threshold of Toxicological Concern (TTC): Designs, Domains & Databases. February 1.

Feb 2011: NA ToxForum (Washington, DC). Assessing Mixtures When Chemical Specific Data are Lacking: Use of the Threshold of Toxicological Concern

Feb 2011: NA ToxForum (Washington, DC). Assessing Risk from Short and/or Intermittent Exposure to Carcinogens: Testing the Framework

Dec 2010: ILSI-Japan (Tokyo, Japan). A Summary of ILSI and HESI Projects on the Threshold of Toxicologic Concern (TTC)

Oct 2010: European ToxForum (Brussels, Belgium). Chair of Session: Assessing Risk from Short and/or Intermittent Exposure to Carcinogens

May – Nov 2010: Invited participant on Expert Group to draft State of the Science report on Animal Alternatives for Carcinogenicity. Published as Adler et al., 2011

December 2009: Refining the Threshold of Toxicological Concern (TTC) for risk prioritization of trace chemicals in food. Invited presentation given to U.S. FDA, Washington, DC.

December 2009: Chaired 3-day International Workshop on "Methods for Intermittent and Short-Term Exposure to Carcinogens" (published as Felter et al., 2011)

November 2009: American College of Toxicology (Palm Springs, CA): Invited presentation on Threshold of Toxicologic Concern: Considerations on the chemical domain and expanding to non-oral exposures.

October 2009: European ToxForum (Brussels, Belgium): Invited presentation on Threshold of Toxicologic Concern: Applications to Personal Care Products.

October, 2008: Invited presentation on Threshold of Toxicologic Concern at PCPC (Personal Care Products Council) Emerging Science of Safety Workshop (Newark, NJ).

July 2008: Chaired ½ day Workshop on the Threshold of Toxicologic Concern at the summer meeting of the Toxicology Forum (Aspen, CO).

March 2008: Chaired ½ day Workshop on the Threshold of Toxicologic Concern at the annual meeting of the Society of Toxicology (Seattle, WA).

September, 2007: Invited presentations on Threshold of Toxicologic Concern and TTC: Case Studies at CTFA Regulatory Science Summit (Washington, DC).

September, 2003: Invited expert peer reviewer to participate in *TERA* workshop to evaluate risk assessment for acrylonitrile.

March, 2001 (also taught in 1995, 1997-2000): Invited lecturer for course on "Environmental Policy Issues." Presented two-day course on toxicology and risk assessment to mid-level managers from various government agencies. Sponsored by the U.S. Office of Personnel Management, Denver, CO

August, 1999: Invited expert peer reviewer to participate in workshop (arranged by *TERA*) to evaluate Health Canada's risk assessment for N-nitrosodimethylamine (NDMA) and ethylene oxide.

November, 1998: Invited as expert peer reviewer to participate in workshop (arranged by *TERA*) to evaluate Health Canada's risk assessment for acrylonitrile.

April 22-24, 1997: Invited lecturer on advances in methodologies for noncancer risk assessment and the basics of cancer risk assessment. University of Cincinnati Risk Assessment course (graduate student)

January, 1997: Invited lecturer for the Department of Environmental Health, University of Cincinnati Seminar Series: Mechanistically-based risk assessment for formaldehyde

Oct. 29 - Nov. 1, 1996: Invited speaker at the International Business Communication Workshop on Risk Assessment. Topic: "Formaldehyde: Role of Mechanistic Data in Cancer Risk Assessment within the Framework of EPA's 1996 Proposed Cancer Risk Assessment Guidelines"

May 21-22, 1996: Invited panel member of U.S. EPA's Peer Review Workshop on "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures"; Bethesda, MD

April, 1996: Invited lecturer on "Genetic Toxicology and Carcinogen Hazard Identification" for University of Cincinnati Risk Assessment Course (graduate student level)

July, 1995: Invited presentation at The Toxicology Forum: "Risks to Human Health from Exposure to Manganese."

Awards

- 2011, 2008: P&G Product Safety & Regulatory Affairs. Technical Excellence Award.
- 2000: P&G Special Appreciation Award from Beauty Care Global Business Unit for the Development of Exposure-Based Risk Assessment guidelines for sensitization.
- 1994, 1993, 1992, 1991, 1990: U.S. EPA Sustained Superior Performance Awards
- 1992: U.S. EPA Bronze Medal for work on Phase V Drinking Water Regulations; U.S. EPA Special Act Award for work on Phase V Drinking Water Regulations.
- 1985-89: Graduate Student Fellowship and Stipend for Tuition at the University of Cincinnati; Recipient of NIOSH Small Grant (1 R03 OH 02657), entitled, "Activation of H-*ras* Oncogene by Drinking Water Disinfectant By-Products"
- 1980: Valedictorian of graduating high school class; Scholarship from IBM (International Business Machines) to attend MIT

Selected Publications:

Felter SP, Daston GP, Euling SY, Piersma AH, Tassinari, MS. 2015. Assessment of health risks resulting from early-life exposures: Are current chemical toxicity testing protocols and risk assessment methods adequate? Crit. Rev. Toxicol., 45(3): 219-244.

Muldoon-Jacobs, K., Boobis, A.R., Barlow, S., **Felter, S.P.,** Hollnagel, H.M., Keller, D., Vitcheva, V., Arvidson, K., Worth, A.P., Yang, C. (2014): Development of non-cancer Threshold of Toxicological Concern (TTC) database to support alternative assessment methods for cosmetics-related chemicals. The Toxicologist – A Supplement to Toxicol. Sci., 138: 419.

Kirsch, T. and **S. Felter.** 2013. Quantitative Risk Assessment for Infant and Children's products based on Child Specific Exposure Considerations. Toxicol. Lett., 221 (Suppl. 28): S227-S228.

Hollnagel, H.M., Ambrosio, M., Boobis, A.R., Cronin, M., **Felter, S.P.,** Keller, D., Muldoon Jacobs, K.L., Safford, R., Vitcheva, V., Worth, A.P., Yang, C. (2013): TTC Task Force: Development of a cosmetics database to support application of TTC to cosmetic ingredients (EU Cosmos project). Toxicol. Lett., 221 (Supplement): S35.

Yang, C., M. Ambrosio, K. Arvidson, S. Barlow, M. Checheva, M. Cronin, **S. Felter**, et al. 2013. Development of New COSMOS oRepeatDose and non-cancer Threshold of Toxicological Concern (TTC) Databases to Support Alternative Testing Methods for Cosmetics Related Chemicals. Abstract. Eurotox, September 2013.

Canady, R., T. McMahon, M. Cheeseman, C. Yang, **S. Felter**, A. Boobis, M. Martin, V. Dellarco, P. Price, M. Laufersweiler, and K. Jacobs. 2013. Application of the Threshold of Toxicological Concern (TTC) Decision Support Approach to Antimicrobial Pesticides. Abstract. Society of Toxicology Annual Meeting, March 2013.

Laufersweiler, M.C, B. Gadagbui, I.M. Baskerville-Abraham, A. Maier, A. Willis, A.R. Scialli, G. Carr, **S.P. Felter**, K. Blackburn, and G. Daston. 2012. Correlation of chemical structure with reproductive and developmental toxicity as it relates to the use of the threshold of toxicological concern. Regul. Toxicol. Pharmacol., 62: 160-182.

Jacobs, K., Arvidson. K., Cronin, M.T., Enoch, S., **Felter, S.P**., Fioravanzo, E., Madden, J.C., Pavan, M., Richarz, A., Safford, R., Worth, A., Yang, C., ILSI EU Expert Group (2012): Development of a new non-cancer TTC database for cosmetics ingredients: a collaborative project between the EC, COLIPA and ILSI Europe. The Toxicologist – A Supplement to Toxicol. Sci., 126: 52.

Felter, S.P., R.B. Conolly, J.P. Bercu et al., 2011. A proposed framework for assessing risk from less-than-lifetime exposures to carcinogens. Crit. Rev. Toxicol., 41(6), 507-544.

Adler, S., D. Basketter, S. Creton, … **S. Felter**, et al. 2011. Alternative (Non-animal) Methods for Cosmetics Testing: Current Status and Future Prospects-2010. Chapter 4. Carcinogenicity. Archiv. Toxicol., 85(5): 367-485.

Boobis A, Budinsky R, Crofton K, Embry M, **Felter S**, Mihlan G, Mumtaz M, Price P, Solomon K, Zaleski R. 2011. Annex B Example case study B: Tier 0 – Substances potentially detectable in surface water. Regul. Toxicol. Pharmacol, 60: S1-14.

Blackburn, K.L., D. Bjerke, G. Daston, **S. Felter,** C. Mahony, J. Naciff, and S. Robison. 2011. Case Studies to Test: "A Framework for Using Structural, Reactivity, Metabolic and Physicochemical Similarity to Evaluate the Suitability of Analogs for SAR-based Toxicological Assessments". Regul. Toxicol. Pharmacol., 60: 120-135.

Boobis, A., R. Budinsky, K. Crofton, M. Embry, **S. Felter**, G. Mihlan, M. Mumtaz, P. Price, K. Solomon, R. Zaleski. 2011. Risk assessment of combined exposure to multiple chemicals: A WHO/IPCS framework. Example case study C: Tier 0—Substances potentially detectable in surface water. Crit. Rev. Toxicol., 41 (5): 369-383.

Boobis, A., R. Budinsky, S. Collie, K. Crofton, M. Embry, **S. Felter,** et al. 2011. Critical analysis of literature on low dose synergy for use in screening chemical mixtures for risk assessment. Crit. Rev. Toxicol., 1-14.

Rai, P., Lee, B.M., Liu, T.Y., Yuhui, Q., Krause, E., Marsman, D., and **Felter, S.** 2009. Safety Evaluation of Disposable Baby Diapers using Principles of Quantitative Risk Assessment. J. Toxicol. Environ. Health., 72(21-22): 1262 – 1271.

Felter, S.P., Lane, R.W., Latulippe, M.E. et al. 2009. Refining the threshold of toxicological concern (TTC) for risk prioritization of trace chemicals in food. Fd. Chem. Toxicol., 47: 2236–2245.

Mahony, C., **S.P. Felter**, and D.A. McMillan. 2006. An Exposure-Based Risk Assessment Approach To Confirm the Safety of Hydrogen Peroxide for Use in Home Tooth Bleaching. Regul. Toxicol. Pharmacol., 44(2): 75-82.

Blackburn, K., J.A. Stickney, H.L. Carlson-Lynch, P.M. McGinnis, L. Chappell, **S.P. Felter**. 2005. Application of the Threshold of Toxicological Concern (TTC) Approach to Ingredients of Consumer Products. Regul. Toxicol. Pharmacol. 43(3): 249-259.

Felter, S.P., J.D. Vassallo, B.D. Carlton, G.P. Daston. 2006. Coumarin: A Quantitative Human Health Risk Assessment Integrating Cancer and Noncancer Endpoints. Fd. Chem. Toxicol., 44(4): 462-75.

Felter, S.P., C.A. Ryan, D.A. Basketter and G.F. Gerberick. 2003. Application of the Risk Assessment Paradigm to the Induction of Allergic Contact Dermatitis. Regul. Toxicol. Pharmacol., 37(1): 1-10.

Felter, S.P., M. K. Robinson, D.A. Basketter, and G.F. Gerberick. 2002. A Review of the Scientific Basis for Default Uncertainty Factors for Use in Quantitative Risk Assessment of the Induction of Allergic Contact Dermatitis. Contact Dermatitis, 47: 257-266.

Gerberick, G.F., M.K. Robinson, **S.P. Felter,** I.R. White and D.A. Basketter. 2001. Understanding fragrance allergy using an exposure-based risk assessment approach. Contact Dermatitis, 45: 333-340.

Casanova, M., R. Conolly, J. Everitt, B. Gross, H. Heck, D. Janszen, J. Kimbell, P. Lilly, F. Miller, K. Morgan, J. Preston, P. Schlosser, R. Subramaniam, **S. Felter**, and J. Overton. 1999. Formaldehyde: Hazard Characterization and Dose-Response Assessment for Carcinogenicity by the Route of Inhalation. Chemical Industry Institute of Toxicology; RTP, NC. Sept. 28.

LaKind, J.S., M.E. Ginevan, D.Q. Naiman, A.C. James, R.A. Jenkins, M.L. Dourson, **S.P. Felter**, C.G. Graves and R.G. Tardiff. 1999. Distribution of Exposure Concentrations and Doses for Constituents of Environmental Tobacco Smoke. Risk Anal., 19(3): 375-390.

Felter, S.P. and M.L. Dourson. 1998. The Inexact Science of Risk Assessment (and Implications for Risk Management). Hum. Ecol. Risk Assess., 4(2): 245-251.

Diamond, G.L., P.E. Goodrum, **S.P. Felter** and W.L. Ruoff. 1998. Gastrointestinal absorption of metals. Drug Chem. Toxicol., 21(2): 223-251.

Felter, S.P. and J.S. Dollarhide. 1997. Acrylonitrile: A re-evaluation of the inhalation database to support a cancer risk assessment. Regul. Toxicol. Pharmacol., 26(3): 281-287.

Felter, S.P., M. Dourson and J. Patterson. 1997. Chapter 2: Assessing Risks to Human Health from Chemicals in the Environment. In: Handbook of Environmental Risk Assessment and Management. P. Calow, ed. Blackwell Science, Oxford.

Felter, S.P. and M.L. Dourson. 1997. Hexavalent chromium contaminated soils: Options for risk assessment and risk management. Regul. Toxicol. Pharmacol., 25(1): 43-59.

Dourson, M.L. and **S.P. Felter.** 1997. Route-to-route extrapolation of the toxic potency of MTBE. Risk Anal., 17(6): 717-725.

Dourson, M.L., **S.P. Felter** and D. Robinson. 1996. Evolution of science-based uncertainty factors in noncancer risk assessment. Regul. Toxicol. Pharmacol. 24: 108-120.

Vater, S.T., **S.F. Velazquez** and V.J. Cogliano. 1995. A Case Study of Cancer Data Set Combinations for PCBs. Regul. Toxicol. Pharmacol. 22: 2-10.

Velazquez, S.F., G. Rice, R. Schoeny and V.J. Cogliano. 1995. Chapter 14: Cancer Risk Assessment: Historical Perspectives, Current Issues, and Future Directions. In: Elements of Risk Assessment. (Ed. A.M. Fan). Marcel Dekker, Inc. NY pp. 219-243.