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Engineering & Scientific Consulting

Beth Polakoff

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Professional Profile

Ms. Polakoff has more than 35 years of multidisciplinary federal, state, and international experience in regulatory and business strategy, residue and metabolism chemistry, exposure and risk assessment, product development and stewardship strategies, and management. She specializes in the development and regulatory approval of new products, as well as support of products throughout their lifecycles, including data compensation and due diligence.

Ms. Polakoff's primary focus is in the pesticide area, including conventional pesticides, biopesticides, and antimicrobial products, and includes products for use in agriculture, horticulture, indoor and outdoor residential settings, and on companion animals and livestock.

Having spent many years in industry and as a consultant, she is particularly adept in the proper use of scientific and risk assessment data to make or impact regulatory decisions, as well as developing strategies to reduce the time needed to begin marketing new products. Ms. Polakoff works to ensure the development of effective integrated regulatory, technical, business, and risk communication strategies. Ms. Polakoff helps clients respond to short-term crisis situations, and works with clients to incorporate long-term strategic regulatory considerations into corporate product and business development processes.

Ms. Polakoff also has extensive experience in the design, direction, and execution of innovative and guideline studies under FIFRA Good Laboratory Practice Standards (GLPs), including market basket surveys, occupational exposure studies, crop field trials and processing studies, residue and exposure mitigation studies, and the development of residue analytical methods.

Academic Credentials & Professional Honors

M.B.A., Strategic Management and Public Policy, George Washington University, 2000

B.S., Chemistry, State University of New York, Purchase, 1984

Member, Beta Gamma Sigma, The Honor Society of AACSB Accredited Business Schools, 2000

Recipient, National Collegiate Business Merit Award, United States Achievement Academy, 1999

Recipient, Merit Award: EU Pesticide Reauthorisation Management, TAS, 1995

Nominee, Uniroyal Quality Award, Uniroyal Chemical, 1989

Recipient, Technical Achievement Award, Uniroyal Chemical, 1988

Recipient, Special ALAR Team Technical Award, Uniroyal Chemical, 1985

Prior Experience

Vice President of the Regulatory Practice, Novigen Sciences, Inc., 2002

Vice President of the Risk Assessment and Chemistry Practice, Novigen Sciences, Inc., 1996-2002

Manager of the Exposure Division, TAS, Inc., 1994-1996

Vice President, Trident Technologies, 1990-1994

Residue Program Coordinator and Analytical Chemist, Uniroyal Chemical, 1984-1990

Professional Affiliations

American Chemical Society, 1984-present

Association of Official Analytical Chemists, 1989-present

American Management Association, 1995-present

National Association of Female Executives, 1999-present

Society of Risk Assessment, 2000-present

American Chemical Society, Agrochemical Division, 1984-present

American Chemical Society, Separations Chemistry Division, 1984-1991

Publications

Book Chapters

Brookman DJ, Curry KK, Polakoff BM. Updated version of best practices in the implementation of a large-scale market basket residue survey study. Chinese Journal of Pesticide Science. Lee PW (ed), Draft version, 2005.

Brookman DJ, Curry KK, Polakoff BM. Best practices in the implementation of a large-scale market basket residue survey study. Handbook of Residue Analytical Methods for Agrochemicals. Lee PW (ed), John Wiley & Sons, Ltd., 2002.

Reports

Tucker KD, Lee K, Caughman CR, Tomerlin JR, Polakoff BM, Kidwell JL. Dietary exposure assessment Phase IV (continued) report, development of summary residue database for dietary exposure assessment. Prepared for DynCorp, Alexandria, VA.

Fleming KH, Sever BE, Tomerlin JR, Chew SB. Consumption of exposure core foods phase IV: 1987-88 NFCS. Prepared for DYN-TAI, Cincinnati, OH, 1996.

Presentations

Long S, Staveley J, Polakoff B, Coler R, Hoberg J, Patnaude M, Rathjen K. Unforeseen Challenges of pollinator toxicity test matrices. Platform presentation, Division of Agrochemicals, Tiered Testing for Pollinator Protection: Experiences in Design, Implementation and Interpretation at the 254th ACS National Meeting, Washington, D.C. August 2017.

Long S, Staveley J, Polakoff B, Coler R, Hoberg J, Patnaude M, Rathjen K. Unforeseen challenges of pollinator toxicity test matrices. Poster presentation, Terrestrial and Wildlife Toxicology and Ecology, SETAC World Congress, Orlando, FL, November 9, 2016.

Li AA, Polakoff B. Analysis of EPA FQPA safety factors for 363 pesticides. Presented in session "Enhancing Strategies for Pesticide Risk Assessment," Society of Toxicology, Phoenix, AZ, March 24, 2014.

Li AA, Polakoff B. FQPA and health effects. Symposium Regulatory Risk Assessment: New Paradigms for Human Health Exposure Considerations for Dietary, Aggregate, Cumulative and FQPA, American Chemistry Society Meeting, Indianapolis, IN, September 12, 2013.

Johnston JE, Polakoff B, Driver J, Ross J. Use of biomonitoring data as surrogate data in regulatory decisions for occupational exposures to pesticides. Presented at the International Society for Exposure Science Annual Conference, Minneapolis, MN, 2009.

Polakoff BM, BenKinney M, Duggan A. EU REACH Regulation: Implications for non-European chemical companies. The 3rd Seminar on Integrated Risk Management, Tokyo, Japan, February 26, 2008.

Polakoff BM. Cumulative risk assessment in the USA. The First Seminar on Integrated Management of Food Risks, Tokyo, Japan, May 15, 2006.

Messina JB, Daniels CL, Polakoff BM, Tucker KD. Registration? But it's a natural product. Presentation at the American Chemical Society National Meeting, New York, NY, September 9, 2003.

Polakoff, BM, Daniel, A., Barraj, LM, Tucker, KD, Harris, CA. Comparison of single-serving market basket survey data to composite monitoring data. Proceedings, IUPAC, Basel Switzerland, August 2002.

Polakoff BM. Pesticides and health risks: Examining new FQPA scientific issues, toxicology, exposure and risk assessment of pesticides. Presentation at the Pesticides Regulations Conference, Washington, DC, September 25, 2001.

Polakoff BM, Osborn DC, Barraj LM. Risk assessment and market basket surveys: Integrated tools for decision-making. Presentation at the Society for Risk Analysis Annual Meeting, Crystal City, Virginia, December 3-6, 2000.

Polakoff BM, Osborn DC. Surveys: An overview. Presentation at the Military Operations Research Society Annual Education and Professional Development Colloquium, McLean, Virginia, April 4-5, 2000.

Youngren SH, Polakoff BM. Children's exposure to pet products: How do we regulate? Presentation at the Society for Risk Analysis Annual Meeting, Atlanta, GA, December 5-8, 1999.

Youngren SH, Walls C, Barraj L, Polakoff BM. Using a calendar method to assess exposure to pesticides applied in the home at different times. Presentation at the Society for Risk Analysis Annual Meeting, Phoenix, AZ, December 6-8, 1998.

Youngren SH, Polakoff BM, Walls CL. Impact of different methods of assessing exposure to pesticides used in the residential environment. Poster presented at the International Society of Exposure Analysis, Boston, MA, August 16-18, 1998.

Youngren SH, Polakoff BM, Walls CL. Advancing non-dietary exposure assessment in the residential environment: The impact of the FQPA. Poster presented at the International Union of Pure and Applied Chemistry, London, UK, August 2-7, 1998.

Polakoff BM. International management and auditing of field studies. Presented at the International Business Communications Conference on GLP in Field and Environmental Studies, New Orleans, LA, February 26-27, 1996.

Polakoff BM, et al. GLP training course for field residue studies. Uniroyal Chemical Co., Inc. Staff Training, Orlando, FL, 1990.

Polakoff BM, et al. The Determination of UDMH residues in crops and tissues using gas chromatography with mass selective detection. ACS National Meeting, Toronto, Canada, 1988.

Parkins MD, et al. Assay of ALAR and its metabolite UDMH. AOAC Northeast Regional Section Meeting, Buffalo, NY, 1986.

Polakoff BM. The determination of acid herbicides in freshwater bodies. American Chemical Society Mid-Atlantic Region Section Meeting, May 1984.

Project Experience

Senior oversight of the strategy, preparation, and submission of successful reduced risk submissions.

Senior review and strategic direction of environmental modeling, drinking water assessments, and ecological risk assessments for EPA, CDPR, and NYSDEC.

Senior review and strategic direction for review and comment on draft human helath, drinking water, and ecological risk assessments from EPA’s registration review.

Oversee and direct all aspects of regulatory and technical support for registration review of a number of compounds.

Global regulatory and technical due diligence for acquisition of an active ingredient. Comprehensive regulatory and technical review of current and anticipated future issues regarding the asset, culminating in recommendations regarding the acquisition.

Senior review of environmental assessments/environmental impact assessments for veterinary pharmaceutical products in the US and EU.

Prepare expert reports for data compensation arbitrations. Findings in reports supported efforts to settle before arbitration.

Testifying expert in data compensation arbitration.

Direct new active ingredient development and registration support projects for food and non-food-use pesticides for the US, Canada, NAFTA Joint Review, and Global Joint Review. Active ingredients consist of insecticides, nematicides, fungicides, herbicides, and plant growth regulators. Direct regulatory strategy and technical data development. Oversee and direct environmental modeling and ecological and human health risk assessment, developing mitigation strategies when needed. Interface with team preparing the public interest or benefits documents and integrate the findings into the regulatory strategy. Interface with the EPA throughout the pre-submission and post-submission processes.

Oversee Total Product Management project in which Exponent has responsibility for handling all

regulatory and technical aspects of US pesticide registration, including new uses, new end-use products, Registration Review, and compiling the data compensation files.

Provide regulatory, technical, and strategy support for pesticide Registration Review, including the preparation of reasoned arguments in support of study waivers, placing and monitoring studies, and the use of risk assessment as a strategic tool prior to or in the early stages of Registration Review.

Provide technical and regulatory support and strategic advice for import tolerance petitions to the US and Canada.

Provide regulatory and technical strategic support for consideration of submitting petitions to the US EPA under FIFRA. Evaluations include data gap analyses and registerability/acceptability analyses of existing data.

Advise clients on regulatory and technical matters at federal and state level in support of pet spot-on product registrations, including data generation and human health risk assessment.

Oversee trans-Atlantic multi-disciplinary team preparing dossier and related global and country specific regulatory and technical support for Global Joint review of a new active substance.

Manage data compensation cost valuations/cost reconstructions in support of clients' negotiations in data compensation matters.

Manage data compensation cost valuations/cost reconstructions in support of cases going to arbitration. Prepare expert reports. Testify as expert witness in data arbitration hearings.

Manage product development activities in support of the registration of new active ingredients, new uses, and new end-use products in the US. These projects include the development of the regulatory strategy, timeline, laboratory recommendations and selection, placing and monitoring studies, human health and environmental risk assessments/modeling, submission of the registration package, and interface with the EPA on the client's behalf.

Advise clients on laboratories to conduct testing for development of new active ingredients for registrations globally. Conducted in-depth meetings and interviews to ascertain the best technical options for the client and compound of interest.

Advise clients on technical and regulatory matters pertaining to child-resistant packaging, in relation to original packaging as well as subsequent modifications to packaging.

Managed a series of Total Product Management projects for a multi-national client, whereby Exponent has global technical and regulatory responsibility for a portfolio of products. Leading multi-year, multi-million-dollar projects, as well as being the primary interface with the client.

Managed the overall regulatory strategy and support of a conventional pesticide currently in the middle stage of development. Coordinated with all technical disciplines in support to develop ascertain the technical issues at hand and to develop an appropriate regulatory strategy and path forward. Recommended strategies for interfacing with the user community (i.e., growers) as part of the overall strategy towards a rapid and successful registration of this product.

Developed regulatory strategies for the development and registration of methyl bromide replacement fungicides. These strategies are for the development of products that are in the early stages of product development. Evaluated the regulatory and grower climate/demand for these products, and likelihood of success in the regulatory arena. Developed strategies that include multiple options for paths forward, such as biopesticide, lower toxicity products under the inert ingredients guidance, or conventional pesticide. Worked with multidisciplinary teams to build successful regulatory strategies based upon the integration of regulatory, technical and business development/marketing objectives and findings.

Managed reduced risk and/or organophosphate (OP) replacement rational petitions in support of expedited review of registration petitions for food (crop pre- and post-harvest) and non-crop uses. Coordinated and working with multidisciplinary teams in the areas of human and environmental risk, toxicology, residue chemistry, efficacy/integrated pest management, and marketing. Developed strategies for the rationale in support of reduced risk and/or OP replacement. Wrote sections of the petition and peer reviewed the documents in their entirety. Met with the EPA's reduced risk committee. Achieved an extremely high success rate in obtaining reduced risk and/or OP replacement.

Designed and managed the conduct of cumulative acute dietary exposure and risk assessments for a class of pesticides used in agriculture. Advised the client, an industry task force, on the regulatory strategy and technical (residue chemistry, metabolism and risk assessment) issues associated with this assessment. Presented findings to the EPA at a joint EPA/Task Force meeting, as well as via a written report.

Managed data compensation-type study valuations in support of client's sale of identified pesticide products.

Advised clients in their due diligence for the potential acquisition of pesticide products of the registrability of the products.

Played a critical role in the conduct of a multiyear market basket survey conducted under FIFRA Good Laboratory Practice Standards (GLPs). Managed the statistical design, field phase, data management and report writing for a nationwide market basket survey of single servings from 13 fresh fruits and vegetables. Advised the study director on analytical residue issues, particularly as they pertained to risk assessment and regulatory strategy. Advised the industry task force on matters pertaining to regulatory strategy and technical implications of the study. Communicated with the EPA, USDA and FDA regarding the study.

Managed the statistical design, field phase and report writing for three other GLP market basket surveys, one task force and two private companies. Advised the study directors on issues, including analytical residue issues, particularly as they pertained to risk assessment and regulatory strategy. Advised the clients on matters pertaining to regulatory strategy and technical implications of the study.

Developed a strategy for the development of a pesticide product line that included crop and non-crop uses to ensure the successful registration of the products within the product line. Used risk assessment as a tool in support of this decision-making process.

Designed first pet dislodgeable study submitted to the US EPA.

Designed, conducted and oversaw dietary, consumer, occupational, drinking water and aggregate exposure and risk assessments on an array of compounds. Addressed pertinent metabolism issue in the context of these assessments.

Co-managing a high production volume (HPV) project, for submission to the OECD, for an industry task force.

Advised a client on an appropriate strategy for a HPV submission to the US EPA.

Advised clients on regulatory and technical strategies and registerability of antimicrobials products.

Advised clients on a spectrum of metabolism issues ranging from regulatory requirements to interpretation of the data to the appropriate handling of the data in risk assessment. Consulted with clients on metabolism issues pertaining to the residue of toxicological concern and the appropriate tolerance expression.

Created and presented training seminars on the Food Quality Protection Act of 1996 (FQPA) for regulatory/technical and business development/marketing audiences.

Managed multidisciplinary teams compiling two dossiers in support of EU re-authorisation under EU Directive 91/414.

Created and presented a training seminar on EU re-authorisation under EU Directive 91/414, including comparisons between the EU and US systems pertaining to MRL/tolerance setting and dietary exposure assessment.

Evaluated the migration of compounds from food packaging materials and manufacturing processes into food in support of intake assessments on these compounds.

Developed a regulatory and technical strategy for obtaining an import tolerance for a Latin American client. Designed the residue program in support of this strategy. Set-up an experimental field station in the Latin American country so that they could conduct the requisite testing under GLPs. Coordinated with the client, the US EPA and representatives from the embassy of this Latin American country in support of this project.

Designed and conducted, as study director, a host of GLP occupational handler (mixer/loader/applicator), exposure (worker re-entry) and foliar dislodgeable studies on a variety of crops in multiple states in support of a pesticide active ingredient's product line. Utilized patch dosimetry, whole body dosimetry and biological monitoring in the exposure testing. Managed the analytical method development/modification and validation in the associated analytical laboratories.

Designed and conducted a GLP occupational exposure study in greenhouses.

Managed and directed the US insecticides and herbicides residue program for Uniroyal Chemical.

Developed a GLP program for the Uniroyal Chemical residue program. Trained all field representatives in GLPs and set-up the two field stations to be GLP compliant.

Conducted residue methods development for pesticide active ingredients and/or their metabolites in fatty and aqueous crops, animal tissues, milk, animal fed, soil and water.

Conducted seminars on interpersonal communications.

Directed product development and financial and marketing strategic planning for a start-up telecommunications firm. Developed and directed customer service. Authored technical and marketing materials.