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Engineering & Scientific Consulting

James B. Messina

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Professional Profile

Mr. Messina has more than 23 years of experience in Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulatory affairs and specializes in pesticide product registration and support at the Federal, State, and International levels; pesticide regulations and policies; EPA registration and support strategies; business strategies; product development; and stewardship. His primary focus is in the area of pesticide regulation, including conventional chemicals, biochemicals, microbial products, and genetically modified organisms (GMOs) in the areas of insecticides, fungicides, rodenticides, antimicrobials, repellents, and plant growth regulators. He focuses on incorporating science, risk assessment, business needs, and regulatory into developing strategies to obtain new product approvals in a timely manner.

Mr. Messina has extensive experience with companion animal products (dogs, cats, and horses) registered as pesticides under FIFRA. This experience includes preparation of EPA registration strategies, data development (companion animal safety studies and efficacy), bridging of data, preparation of EPA submissions, and successful approval of EPA pesticide active ingredients and/or products.

Academic Credentials & Professional Honors

B.S., Natural Resource Management/Environmental Science, University of Maryland, 1992

Prior Experience

Project Manager, Novigen Sciences, Inc., 2001-2002

Senior Registration Manager, Thermo Trilog Corporation, 1998-2001

Senior Product Manager, Jellinek, Schwartz & Connolly, Inc., 1996-1998

Product Manager, Jellinek, Schwartz & Connolly, Inc., 1994-1995

Assistant Product Manager, Jellinek, Schwartz & Connolly, Inc., 1993-1994

Wildlife Research Assistant Volunteer, U.S. Fish & Wildlife Service, 1992-1993

Biological Technician, U.S. Department of Agriculture, 1989-1990

Professional Affiliations

Member of Biopesticide Industry Alliance — BPIA, 2002-present

Member of Responsible Industry for a Sound Environment — RISE, 2002-present

U.S. Coast Guard Merchant Marine Officer, 2002-present

Publications

Messina JB. New US EPA regulatory requirements for adjuvants. Proceedings of the 9th International Symposium on Adjuvants for Agrochemicals, ISAA Society, pp. 213-220, 2010.

Presentations

Messina JB. Inert ingredient EPA regulation and the JITF history. Presentation at the Chemical Producer and Distributors Association Summer Conference and Annual Meeting, Nashville, TN, August 4, 2015.

Messina JB. New US EPA regulatory requirements for adjuvants. Presentation at the 9th International Symposium on Adjuvants for Agrochemicals, Freising, Germany, August 16, 2010.

Messina JB. The Joint Inerts Task Force (JITF), an effective task force model. Presentation at the American Chemical Society National Meeting, San Francisco, CA, March 21, 2010.

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.

Project Experience

Specializes in providing FIFRA regulatory support for new active ingredients, registered active ingredients, food-use and non-food use pesticide products, new end-use products, new uses of registered products, and supplemental/distributor registrations.

Managed international registration efforts for pesticide products in Canada, Mexico, Europe, Central America, South America, Australia, and Asia.

Managed the data development for multiple active ingredients and end-use products in support of Federal and State pesticide registration, EPA registration review, EPA re-registration, special reviews, and other data requirements under FIFRA. This work included general regulatory consulting services, coordination of client and laboratory interactions, and managing and monitoring ongoing health and safety studies at contract laboratories.

Managed multiple industry task forces. He was the Administrative Manager for an industry task force focused on the reinstatement of tolerance exemptions for inert (other) ingredients. This work involved development of a strategic plan for each group of inert ingredients, implementation of the strategy, placement, and monitoring of toxicology data, preparation and submission of petitions for tolerance exemption, and tracking of EPA submissions to approval.

Expert in obtaining new inert (other) ingredient approvals for food-use and non-food use through EPA's Chemistry, Inerts, and Toxicology Assessment Branch. This work involved development of an EPA regulatory strategy, outline of appropriate data requirements, implementation of the strategy, and preparation and submission of petitions for the new inert ingredient (including tolerance exemption petitions for food-use products).

Supported new chemical products under the Toxic Substance Control Act (TSCA), including preparation

and submission of Pre-Manufacture Notices (PMNs), Low Volume Exemptions (LVEs), Polymer Exemptions, Significant New Use Notices (SNUNs), Significant New Use Rules (SNURs), Notices of Commencement of Manufacture (NOCs), Risk Assessments, and Chemical Import Issues.

Experienced in evaluating data compensation, study valuations, and cost reconstruction in support of clients' negotiations in data compensation matters.

Advised clients on regulatory and technical matters related to child-resistant packaging and required testing.

Managed reduced risk EPA petitions in support of expedited review of applications for registration for food and non-food uses. Developed the strategy and rationale to support the submission.

Performed due diligence reviews of pesticide products and supporting data for potential acquisition.

Performed EPA FIFRA training for clients.

Provided regulatory and technical support for Global Review and NAFTA submissions for new active ingredients.

Prepared multiple tolerance exemption petitions for polymers (qualifying for polymer exemption), including submission of all supporting data and tracking of the EPA review and approval of the new food-use polymer inert ingredient and associated tolerance exemption.

Prepared and submitted multiple new non-food use inert (other) ingredient petitions to EPA.

Provided data compensation negotiation support for registration of pesticide product under FIFRA. Performed evaluation and valuation of data. Directed data compensation negotiations between companies.