Message

From: KOCH, MICHAEL S [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=MSKOCH]
Sent: 5/19/2016 5:24:39 PM
To: REDACTED
Subject: Koch CV 2016.docx
Attachments: Koch CV 2016.docx

Please see attached.

Curriculum Vitae

Michael S. Koch, PhD, DABT

Address: **REDACTED** **Contact:** **REDACTED** Mobile
e-mail: **REDACTED**

Education

PhD, Pharmacology, University of Iowa College of Medicine, Iowa City, IA

BS, Biology, Maryville University, St. Louis, MO

Work Experience

Monsanto, St. Louis, Missouri, July 12, 2010 to Present

Product Safety Center, Lead: December 1, 2015 to Present

Job Description / Responsibilities:

The Product Safety Center consists of the Macromolecule Toxicology Team (which evaluates the safety of biotechnology-derived products), the Small Molecule Toxicology Team, and the Compositional Biology Team. The Product Safety Center Lead oversees the conduct of toxicological evaluations of biotechnology-derived, chemistry, and microbial products; and the compositional analysis of biotechnology-derived crops as described by the Codex Alimentarius Commission of the World Health Organization. The role provides scientific oversight and direction, and people leadership to both the Toxicology and Composition teams as they plan, conduct, and interpret studies comprising two key aspects of the regulatory submissions, and global scientific outreach, for biotechnology-derived products. The role leverages productive collaborations with Monsanto stakeholders and external bodies (national research institutes, international trade associations, and national regulatory agencies) to navigate, and shape, a complex international regulatory environment and gain regulatory approvals and freedom-to-operate for the company's products. To accomplish this, the Product Safety Center Lead must identify strategic challenges to the development of new products and the defense of existing products, develop plans to address those technical and regulatory challenges, collaborate with Monsanto's Regulatory and Government Affairs Leadership Team to implement near-term and long-term technical strategies, and delegate/oversee the generation of the data which addresses those challenges. Writing or overseeing the development of relevant white papers and journal articles are a frequent outcome of these collaborations.

Major responsibilities include: people leadership and development of the entire Product Safety Center; empowering the teams to conduct, analyze, and report high-quality toxicology, animal nutrition, and compositional studies and risk assessments; ensuring stewardship of Monsanto's products through characterization and communication of potential hazards for human health; and leading industry-wide collaborations to align on study and risk assessment methodology, develop scientific positions, and engage in dialogue with regulators. Additional responsibilities include leading relationship development and maintenance with external laboratory partners to ensure high quality, efficient, and cost

effective data generation; and management of timelines and budgets to ensure Regulatory objectives are met.

Toxicology and Nutrition Center, Lead: September 1, 2014 to November 30, 2015

Job Description / Responsibilities:

The Toxicology and Nutrition Center Lead enables registration, secures freedom to operate, and ensures appropriate product stewardship of a diverse product portfolio through high quality assessments of the potential impact of Monsanto's products on human health or human and animal nutrition. The role also is responsible for providing scientific direction and people leadership to a multi-disciplinary team responsible for conducting toxicology and nutritional studies used in Regulatory submissions and scientific outreach globally. The role requires cultivating productive internal collaborations with stakeholders including Monsanto's Biotechnology and Chemistry Regulatory Affairs, Regulatory Pipeline Strategy, Regulatory Sciences, Biotechnology, Chemistry Technology, Stewardship and Quality Assurance organizations; and fruitful external collaborations research institutes (e.g., Russia Institute of Nutrition, China Agricultural University) and international trade associations. Success in the role requires effective communication with a diverse range of stakeholders and audiences on wide variety of topics (i.e., global data submission strategies, methodologies, and role of toxicology and nutritional assessments in a complex and international regulatory environment, etc.); including consultations with national regulatory agencies (e.g., the European Food Safety Authority, Health Canada, China's Ministry of Agriculture) on the quality and robustness of safety data submitted with a product's application. Such collaborations often result in toxicology white papers and journal articles advocating for science-based regulations and risk assessments.

Major responsibilities include: people leadership and development; empowering the team to conduct, analyze, and report high-quality toxicology and nutrition studies and risk assessments; ensuring stewardship of Monsanto's products through characterization and communication of potential hazards for human health; and leading industry-wide collaborations to align on study and risk assessment methodology, develop scientific positions, and engage in dialogue with regulators. Additional responsibilities include building global strategies for safety assessment of new products; leading relationship development and maintenance with external laboratory partners to ensure high quality, efficient, and cost effective data generation; and management of timelines and budgets to ensure Regulatory objectives are met.

New Technologies in Toxicology, Lead: October 1, 2012 to September 1, 2014

Job Description / Responsibilities:

The New Technologies in Toxicology Lead is responsible for the design and conduct, or overseeing the design and conduct of, toxicology studies with biotechnology-derived products to support regulatory applications, regulatory re-registrations, freedom-to-operate efforts, and other toxicology-related projects. This role also provides data analysis and interpretation in preparation for final reports, performs quality control checks on documents intended to support regulatory submissions, and ensures compliance. Interfaced with key internal stakeholders to consult and collaborate on research projects with multidisciplinary teams consisting of subject matter experts in chemistry, protein sciences, molecular biology, toxicology, and pathology to develop/defend products. This requires one to maintain broad

knowledge of state-of-the-art scientific principles and theories in the disciplines mentioned above as well as current toxicological principles and theories. It also provides the opportunity to investigate the feasibility of applying a wide variety of scientific principles and concepts to challenges in the safety assessment of biotechnology-derived products. The New Technologies in Toxicology Lead is also expected to make major contributions to scientific literature and conferences in the form of manuscripts, abstract, and presentations. Additional responsibilities include identifying, developing, and collaborated with management on near-term and long-term business strategies relating to the development of new products and the defense of existing products. Also, the New Technologies in Toxicology, Lead advises team members on project management and the resolution of technical problems.

Toxicologist; Emerging Leaders in Science PhD Rotational Program: July 12, 2010 to October 1, 2012

Job Description / Responsibilities:

Primarily responsible for providing global toxicology and risk assessment support for crop protection chemicals and new food crops developed through biotechnology or conventional breeding by the initiation and monitoring of mammalian toxicology studies with chemical and biotechnology-derived products at outside contract laboratories. Additional responsibilities include conducting human health risk assessments and providing toxicology support for regulatory submissions around the world. These responsibilities are accomplished in collaboration with a diverse group of toxicologists, ecotoxicologists, human and animal nutritionists, biochemists, molecular biologists, and residue and metabolism chemists in a dynamic, team-oriented environment.

The Emerging Leaders in Science PhD Rotational Program is a training and mentoring program that immerses its members in a comprehensive, cross-functional experience within Monsanto. The program consists of three, one-year rotational assignments strategically selected to initiate and facilitate the development of scientific and leadership skills that compliment the experiential learning offered in each role. Throughout the three-year program the members will work with, and be mentored by, some of Monsanto's most talented scientific leaders. Upon completion of the program the members will emerge prepared to lead efforts focused on agricultural innovation in key roles within Monsanto’s Technology Organization.

Seventh Wave Laboratories, Chesterfield, MO, February 2008 to June 2010

Exploratory Toxicology and Pharmacokinetic Study Director

Job Description / Responsibilities: Primarily responsible for designing experiments to assess the tolerability and pharmacokinetics of small molecule and biological test articles *in vivo*. As a Study Director, responsibilities included protocol development and/or review of non-regulated studies supporting registration of agricultural, chemical, pharmaceutical, and biotechnology products. Duties included study scheduling and monitoring, review of IACUC protocols, resource coordination, facilitating dose formulation, data analysis including final determinations of test article affect, and reporting results. Acted as a liaison between staff and client to ensure both internal and client expectations for quality and timeliness were met. Assisted in the development and continuous improvement of best practice procedures for various study activities. Interfaced with client product teams regarding product testing strategies, and assisted in the development of specialized techniques to meet study objectives.

In-Life Group Manager

Job Description / Responsibilities: The In-Life Manager has overall responsibility for the In-Life group at Seventh Wave. The responsibilities of the In-Life Manager included the following: oversaw the development, implementation and maintenance of processes that assure the proper functioning of the In-Life group; assured that the In-Life group adhered to testing facility procedures supporting compliance with applicable regulations; conducted performance reviews and made hiring decisions for the In-life group; strategic planning and oversight of resource allocation for the In-Life group; oversaw the development of programs for the preventative maintenance, monitoring, and calibration of laboratory equipment; provided technical input during protocol development; assisted the Study Coordinators in conveying timely communication to the Principle Investigator or Study Director of any protocol deviations or significant Best Practice deviations.

WIL Research Laboratories, Ashland, OH, February 2006 to February 2008

Toxicologist

Job Description / Responsibilities: Study Director for acute, subchronic, and chronic general toxicology studies intended for regulatory submission to FDA and EPA. Duties included the preparation of Protocols, study schedules, Standard Operating Procedures, and study cost estimates; project management of preclinical toxicity studies; evaluation of study data collected and preparation of reports. Served as scientific representative on the Institutional Animal Care and Use Committee and the 21 CFR Part 11 Compliance Committee.

Dept. of Pharmacology, University of Iowa, Iowa City, IA, August 1996 to October 2005

Graduate Research Assistant and Doctoral Candidate

Co-developed research plan to further characterize the cellular targeting and trafficking of Myelin Oligodendrocyte Glycoprotein. Prepared abstracts and manuscripts and presented novel data at laboratory, departmental, and national scientific meetings. Taught an undergraduate course in which basic pharmacological principles and pharmaceutical mechanisms of action were explained to non-scientists. Upon the arrival of junior laboratory members and intern undergraduate students helped train them in laboratory-specific scientific techniques.

Publications and Abstracts

- Petrick, J.S., Frierdich, G.E., Carleton, S.M., Kessenich, C., Silvanovich, A, Zhang, Y., and Koch, M.S. Corn Rootworm Active RNA DvSnf7: Repeat Dose Oral Toxicology Assessment to Support Human and Mammalian Safety. (In preparation).

- Wang, C., Glenn, K., Kessenich, C., Bell, E., Burzio, L., Koch, M.S., Li, B., and Silvanovich, A. Safety assessment of dicamba mono-oxygenases that confer dicamba tolerance to various crops. (In preparation).

- Koch, M.S., DeSesso, J.M., Williams, A.L., Michalek, S., Hammond B. Adaptation of the ToxRTool to assess the reliability of toxicology studies conducted with genetically modified crops and implications for future safety testing. Crit Rev Food Sci Nutr. 2016 Feb 17;56(3):512-26.

- Koch, M.S., Ward, J.M., Levine, S.L., Baum, J.A., Vicini, J.L., Hammond, B.G. The food and environmental safety of Bt crops. Front Plant Sci. 2015 Apr 29;6:283.

- Wang, C., Burzio, L.A., Koch, M.S., Silvanovich, A., Bell, E. Purification, characterization and safety assessment of the introduced cold shock protein B in DroughtGard maize. Regul Toxicol Pharmacol. 2015 Mar;71(2):164-73.

- Petrick, J.S., Moore, W.M., Heydens, W.F., Koch, M.S., Sherman, J.H., Lemke, S.L. A 28-day oral toxicity evaluation of small interfering RNAs and a long double-stranded RNA targeting vacuolar ATPase in mice. Regul Toxicol Pharmacol. 2015 Feb;71(1):8-23.

- Koch, M., Burzio, L., Finnessy, J., Kaempfe, T., Kang, H., Silvanovich, A., Wang, C. and Bell, E. Safety Assessment of Dicamba Monooxygenase from the Biotechnology-Derived Soybean MON 87708. SOT Annual Meeting, 2013.

- Hammond, B.G. and Koch M.S. A Review of the Food Safety of Bt Crops. In E. Sansinenea (ed.), *Bacillus thuringiensis* Biotechnology (pp 305-325). New York: Springer Science+Business Media, 2012.

- Koch, M.S., Melton, R.J., Xiao, D. and Vick, A. The effect of increasing DMSO concentrations on the pharmacokinetic profile of orally dosed reserpine in male Sprague Dawley rats. SOT Annual Meeting, 2010.

Invited Presentations

- "Human Safety Considerations for Dietary RNA." Chinese Academy of Sciences – Institute of Biophysics; Beijing, China.

- "Global toxicity assessment practice for biotech products." Workshop on Safety Assessment of Agricultural Biotech Crops; Lijiang, China.

- "Pesticide Safety and Glyphosate." Workshop on Pesticide Safety; Bogor, Indonesia.

- "Regulatory Toxicology as a Career Path." University of Georgia Interdisciplinary Toxicology Program; Athens, Georgia.

- "Regulatory Toxicology as a Career Path." Iowa State University Interdepartmental Toxicology Program; Ames, Iowa.

Professional Affiliations

Toxicology Forum Board Member

Diplomate of the American Board of Toxicology (Certified 2009, Re-certified 2014)

Member of the American College of Toxicology

Member of the Society of Toxicology