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Professional Profile

Mr. Warren is a board-certified toxicologist with an excellent understanding of EU regulatory risk assessments and testing strategies. He has a particular interest in CMR ("Carcinogenicity, Mutagenicity, toxic to Reproduction") classification under the Classification, Labelling and Packaging regulation. With over 30 years of experience in regulatory toxicology, he has particular strengths in carcinogenicity, reproductive toxicity, clinical pathology, toxicological modes of action, and evaluation of endocrine active chemicals. Mr. Warren has developed and refined human health risk assessments for numerous agrochemicals, biocides and industrial chemicals; and has provided effective and helpful technical support of substances at meetings of European Chemical Agency's Risk Assessment Committee.

Mr. Warren conducted more than 120 studies during 15 years in CRO and industry laboratories. During this time, he obtained his Diploma of the Institute of Biology in Toxicology, and the Diploma of the Royal College of Pathologists. He also attained American Board certification (Diploma of the American Board of Toxicology) before moving to the UK's Pesticides Safety Directorate where he became the Head of the Mammalian Toxicology Branch.

Between 1997 and 2000, Mr. Warren was the chairman of several technical (ECCO) meetings of international regulators agreeing European harmonized toxicology assessments for agrochemicals under Directive 91/414 EEC, and had a leading role in forming the risk assessment procedures adopted at those meetings. In 1998, he was a temporary adviser to the Joint Meeting on Pesticide Residues. An enthusiast for continued professional development, he was an active member of the British Toxicology Society's Education Sub-Committee from 1999-2000, and chaired a BTS seminar on professional toxicology certification in Spring 2000 before moving to the U.S. later that year.

As a consultant, Mr. Warren has been particularly successful in defending or revising NOAELs, designing key supplementary or mechanistic studies, waiving costly and time-consuming studies for minor uses, and critically assessing conflicts between published research and known regulatory results. Mr. Warren's first-hand familiarity with European regulatory processes permits fine judgment on the level of data required for regulatory comfort. Past experience includes investigation of mechanisms of endocrine disruption, and of interpretation of data for classification of chemical hazard under the Classification, Labelling and Packaging Regulation (EC) No 1272/2008 and GHS with particular respect to specific target organ toxicity and the "CMR"s. Mr. Warren's expertise is particularly relevant to EU regulation under the Plant Protection Products Regulation (EC) No 1107/2009, the Biocides Regulation (EU) No 528/2012 and REACH (EC) No 1907/2006.

Academic Credentials & Professional Honors

M.Sc., Pharmacological Biochemistry, The Hatfield Polytechnic, UK, 1984

B.Sc., Biological Sciences, University of Aston in Birmingham, UK, *Hons*, 1977

Diploma of the American Board of Toxicology 1994 (re-certified 2009)

Diploma of the Institute of Biology in Toxicology (with Merit), 1994

Diploma of the Royal College of Pathologists, Toxicology, 1993

Prior Experience

Head of Toxicology Branch (previously Senior Scientific Officer), UK Pesticides Safety Directorate, 1995-2005

Group Leader and Study Director, Sandoz Agro, 1986-1995

Study Director, Huntingdon Research Centre, 1978-1986

Professional Affiliations

Institute of Biology (MIBiol; also Chartered Biologist, CBiol) (member since 1981)

British Toxicology Society (member 1994)

Diplomate, Royal College of Pathologists (member 1993)

Society of Toxicology (member 2005)

Languages

German

Publications

Warren S, Manibusan M. The New EU Endocrine Disruptor Sientific Criteria: What are the Regulatory Implications? Program No. 2172, Society of Toxicology, Baltimore MD, 2017.

Warren S, Freeman E. Interaction between Globally Harmonised System (GHS) and Chemical Registrations in the EU. Program No. 1919, Society of Toxicology, San Diego CA, 2015.

Warren S, Freeman E, Reddy J. Overview of the Existing Regulations and Testing Programs for Endocrine Active Chemicals. EUROTOX 2013, Interlaken, Switzerland, 2013.

Marrs TC, Warren S. Haematology and Toxicology. In: General and Applied Toxicology, 3rd Edition. Ballentyne B, Marrs TC, Syversson T (eds). John Wiley & Sons Ltd., London, 2009. (also 2nd Edition, 1999).

Li AA, Kedderis GL, Warren S, McIntosh LJ. Pesticide risk assessment and animal models of PD. Program No. 1254, Society of Toxicology, Baltimore, MD, 2009.

Warren S. Interpretation of dermal absorption for pesticides and biocides in the EU: A limited critique of EU guidance. Programme No. 1499, Society of Toxicology, Baltimore, MD, 2009.

McIntosh LJ, O'Callaghan JP, Benkovic SA, Miller DB, Patten R, Collier MJ, Switzer RC, Warren S, Li AA. Dose-response evaluation of C57Bl/6 mice for motor abnormalities and parkinson-patterned

neuropathology after Paraquat and Maneb exposure. Program No. 2120, Society of Toxicology, Baltimore, MD, 2009.

Warren S. Data Waiving under EU Directive 98/8/EC (Biocidal Products Directive): a practical example sparing approximately 2,000 animals in registration of a rodenticide. Progrom No. 904, Society of Toxicology, San Diego CA, 2006

Harris CA, Mascall JR, Warren SFP, Crossley SJ. Summary report of the international conference on pesticides residues variability and acute dietary risk assessment. Food Addit Contam 2000; 17(7):481-484.

Project Experience

Design, placement, and regulatory presentation of a series of studies investigating a dog-specific thyroid toxicity for an agrochemical, demonstrating the mode of action falls outside the EU criteria for endocrine disruption.

Critical review of published testicular toxicology results for an insecticide; comparing to regulatory data, demonstrating critical flaws in the published study; preventing erroneous classification and relieving requirement for new regulatory multigeneration studies.

Designed and monitored an abbreviated study of methaemoglobin formation by an agrochemical, providing an acceptable Acute Reference Dose at minimum cost and use of animals.

Design and interpretation of a study of prolactin and reproductive hormones in rats, to address mechanisms of Leydig cell tumour formation with respect to classification for carcinogenicity under Directive 67/548EEC.

Participated in design and conduct of a study of thyroid function and hepatic enzyme induction in rats, investigating a possible mechanism of carcinogenesis.