

Simon F.P. Warren, DABT, DIBT, DipRCPath
Managing Scientist

Professional Profile

Mr. Simon Warren is a board-certified toxicologist in Exponent's Health Sciences Center for Chemical Regulation and Food Safety. He has excellent understanding of the application of toxicology data to regulatory risk assessments, and whose expertise includes reducing animal use to the minimum necessary through careful study design and by best use of existing data.

Mr. Warren has over 20 years of regulatory toxicology experience, having 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 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 Dangerous Substances Directive 67/548EEC (now the Classification, Labelling and Packaging Directive, or GHS) with particular respect to specific organ toxicity (R48) and the "CMR"s - carcinogenicity (R40), mutagenicity, and toxicity to reproduction (R62 and R63). Mr. Warren's expertise is particularly relevant to EU regulation under the new Authorisation Regulation (EC) No 1107/2009, the Biocides Directive (98/8 EC) and REACH.

Academic Credentials and Professional Honors

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

B.Sc., Biological Sciences (Hons), University of Aston in Birmingham, UK, 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

Languages

German

Publications

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. Programme No. 2120, Society of Toxicology, Baltimore, MD, 2009.

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.

Presentations

Warren SFP (organizer and chairman). Undertaking professional diplomas in toxicology. British Toxicology Society Spring Meeting, March 2000.

Warren SFP. Case studies: Pesticide. The Henry Stewart Conference on Perception, Communication and Management of Risks to Health, April 1997.

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

Project Experience

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.

Developed “Justification for Non-Submission” of carcinogenicity, chronic toxicity and multigeneration studies for a biocide, using non-guideline and read-across data thus sparing the costs and animals involved in these studies. This represents one of the major “non submission” successes to date under the EU Biocides Directive.

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.

Professional Associations

- Institute of Biology (MIBiol; also Chartered Biologist, CBiol) (member 1981)
- British Toxicology Society (member 1994)
- Diplomate, Royal College of Pathologists (1993)
- Society of Toxicology (2005)