

## **bibra – toxicology advice & consulting**

### **A résumé of major projects involving bibra toxicologists**

One of the unique strengths of the **bibra** team of toxicologists is the extraordinary length of time that they have worked together, resulting in an operational efficiency that ensures high project quality and cost-effectiveness. Each team member brings specific individual skills, generating a community strength across a comprehensive range of toxicological (and epidemiological) end-points. The same team ethic drives the company's unmatched efficiency in database searching and data identification.

To reflect the power of this team expertise and performance and to assist clarity (by avoiding repetition in the specific and multiple listing of projects in individual CVs), we felt it would be easier on the reader if we provide brief summaries of the major projects that **bibra** (in all its guises – see history on page 12), has worked on in the last 20 years, along with the names of those who worked on each project.

Please contact us if you would like to see a detailed CV for any individual member of our staff.

## Corporate CV

Project	Project Team
<p style="text-align: center;"><b>bibra</b></p> <p>Bibra provides an information and advisory service on all aspects of chemical toxicological hazard and risk, and on the associated legislation. The following examples illustrate the nature of some of the projects that have been undertaken.</p>	
<p style="text-align: center;"><b>REACH</b> <i>(Registration, Evaluation, Authorisation and Restriction of Chemicals)</i></p>	
<p>Assistance on REACH registration tasks including:</p> <ul style="list-style-type: none"> <li>• Searching both internal and external information sources for data on toxicity, ecotoxicity, physicochemical properties and environmental fate</li> <li>• Preliminary categorization and analysis of read-across possibilities</li> <li>• Evaluating and summarizing papers/study reports, IUCLID 5 filling, and preparation of robust summaries (Dossier preparation)</li> <li>• Initial data gap analysis, in readiness for generation of Integrated Testing Strategies (ITS) and data waivers</li> </ul>	<p>Philip Copestake Margaret Davies Tanya Diver Anne Edwards James Hopkins Peter Watts Richard Young</p>
<p>In regard to hazard classification needs under REACH, GHS and the new EU Classification and Labelling Directive (1272/2008), independent classification of many hundreds of substances used in consumer products</p>	<p>Christina Anderson Tanya Diver Anne Edwards James Hopkins Tracy Laughland Emma Russell Peter Watts Richard Young</p>
<p>Supply of TRACE toxicity database bibliographic printouts for REACH pre-registered substances to a large manufacturing company, as part of the critical, early data-gathering step in dossier preparation. TRACE appears in REACH guidance on Information gathering as a useful source of toxicity information</p>	<p>Richard Young Peter Watts</p>
<p>Expert searches of recent literature for new data on a substance for a SIEF, to update existing knowledge of the literature. Also, summary and robust summary preparation of new studies in IUCLID 5 format</p>	<p>Philip Copestake Richard Young</p>
<p>Organising (Q)SAR analyses (DEREK and TOPKAT) to predict the toxicity of untested substances. Receiving the model outputs, searching more recent literature and producing accompanying reports</p>	<p>James Hopkins Peter Watts</p>

<b>Project</b>	<b>Project Team</b>
Identification of CMRs, PBTs and vPvBs amongst a downstream user's large portfolio of supplied substances	Philip Copestake Peter Watts
Assistance with identification of information for the pre-registration of several hundred ingredients of a consumer product	Philip Copestake Richard Young
<b><i>Food and Consumer Products sector</i></b>	
Hazard and risk assessments relating to contaminants in food and drink. Examples of contamination scenarios include: (a) migration of packaging material components (b) residues of processing aids (c) cross-contamination due to use of common equipment (d) contamination during manufacture due to equipment failure (e) pesticide residues (f) decomposition products	Philip Copestake Margaret Davies James Hopkins Tanya Diver Peter Watts
Safety-in-use opinions (risk assessments) on multi-component formulations, including food-contact inks, adhesives, coldseals and food-contact matrices	Peter Watts Philip Copestake Tanya Diver Anne Edwards James Hopkins Tracy Laughland Judy Ricketts Emma Russell Richard Young
Preparation of succinct overviews on the occurrence, intake and toxicology of food contaminants	Philip Copestake Margaret Davies Tanya Diver Anne Edwards James Hopkins Tracy Laughland Peter Watts Richard Young
Urgent hazard and risk assessment on a surface contaminant of a consumer product likely to come into contact with human skin	James Hopkins Peter Watts
Hazard and risk assessments of water contaminants	James Hopkins
Risk assessment of a sanitizing process for use in food factories	Tanya Diver James Hopkins
Safety evaluation of a flavouring product for use in beer production	Tanya Diver James Hopkins Richard Young

<b>Project</b>	<b>Project Team</b>
Secondment of a senior toxicologist to assist a member company during the introduction of a Product Lifecycle Management (PLM) system and, together with a junior toxicologist, in periods of the client's staff shortages	Philip Copestake Richard Young
Critical summaries of the toxicological status of food additives	Christina Anderson Philip Copestake Margaret Davies Tanya Diver Anne Edwards James Hopkins Tracy Laughland Judy Ricketts Emma Russell Peter Watts Richard Young
Hazard assessments of a wide range of plant-derived extracts with potential use as nutraceuticals	Philip Copestake Margaret Davies Tanya Diver Anne Edwards James Hopkins Tracy Laughland Judy Ricketts Emma Russell Peter Watts Richard Young
Hazard and risk assessments related to probiotics intended for food use	Philip Copestake Margaret Davies Emma Russell
Summaries of toxicity data, with an emphasis on carcinogenicity, mutagenicity and reproductive toxicity, on several hundred flavourings and fragrances used in various consumer products	Christina Andersen Philip Copestake Margaret Davies Tanya Diver Anne Edwards James Hopkins Tracy Laughland John Phillips Judy Ricketts Emma Russell Peter Watts Richard Young
Critical review of the literature on the role and value of currently used genotoxicity screening tests to predict mammalian carcinogenicity	James Hopkins Tanya Diver Emma Russell
Reviews of the literature on the skin absorption of heavy metals, such as antimony, arsenic, cadmium, lead and mercury	James Hopkins Philip Copestake Emma Russell Anne Edwards

<b>Project</b>	<b>Project Team</b>
Classification of over 500 ingredients of consumer products by the Cramer, Ford and Hall decision tree and by Toxtree	Peter Watts John Phillips
Application and evaluation of structure activity methodology	Peter Watts John Phillips James Hopkins Tanya Diver Emma Russell
Assessment of a molecule for the presence of any structural alerts which have been linked with DNA reactivity or genotoxic carcinogenicity by Tennant and Ashby (1991), and using the decision tree approach of Cramer, Ford and Hall (1978) and Toxtree to identify any functional groups that might be indicative of significant toxicity	Philip Copestake Anne Edwards Peter Watts
Critical evaluation of the neurobehavioural toxicology of a food additive class	Tanya Diver Margaret Davies James Hopkins
Comparison of two salts of a metal, to assist in reaching a substitution decision	Anne Edwards Peter Watts
<b><i>Chemicals sector</i></b>	
<b>REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)</b>	
Assistance on REACH registration tasks for a number of chemical companies (please see page 2 of this CV for further details)	
Completion of study summaries, filling of data gaps and preparation of data waivers for a Biocidal Products Registration project	Philip Copestake Tanya Diver Anne Edwards Peter Watts
Hazard and risk assessments on chemicals encountered in the workplace	Christina Anderson Philip Copestake Tanya Diver Anne Edwards James Hopkins Tracy Laughland Judy Ricketts Emma Russell Peter Watts
Hazard and risk assessment of low-dose exposures experienced by the general population as a result of industrial emissions	James Hopkins Peter Watts

<b>Project</b>	<b>Project Team</b>
Derivation of proposed Workplace Exposure Limits for chemicals without existing quantitative guidance, and comments on existing values	James Hopkins Peter Watts
Advice on complex toxicological issues related to inter-supplier differences in CHIP classification and labelling. Recommendations on appropriate classification to ensure compliance with CHIP	Philip Copestake James Hopkins Emma Russell Peter Watts
Providing advice to a Hong Kong planning tribunal on toxic materials used in tunnel construction	James Hopkins
Chemical hazard assessments supplied for due diligence purposes	Peter Watts Emma Russell James Hopkins
Preparation of "position papers" on important chemicals of high concern that have found their way into various environmental media e.g. POP chemicals	Margaret Davies Peter Watts Richard Young
Providing SDI services such as regular literature searches on chemicals or chemical groups e.g. plasticizers, identifying the key toxicological data, and preparing evaluative summaries	Philip Copestake Christina Anderson Tanya Diver
<b><i>Pharmaceuticals sector</i></b>	
Hazard reviews and risk assessments on excipients, contaminants and impurities (including genotoxic impurities) in pharmaceutical products (including parenteral nutrition products)	Philip Copestake James Hopkins Peter Watts Richard Young
For due diligence purposes, hazard assessment of a pharmaceutical active ingredient	James Hopkins
Safety-in-use opinions on formulations used in a medical product in close and regular contact with skin	Tanya Diver James Hopkins Peter Watts Richard Young
A review of the toxicological hazards of an inorganic ion, and an evaluation of the health risks posed by the release of the ion from a pharmaceutical product	Christina Anderson James Hopkins
A review of the non-clinical toxicology of an active	Philip Copestake Emma Russell
Risk assessment of a component of a resin for use in medical procedures	Tanya Diver James Hopkins
Risk assessment of a sanitizing process for use in hospital wards	Tanya Diver James Hopkins

<b>Project</b>	<b>Project Team</b>
Numerous hazard reviews on individual substances to assist in the preparation of safety data sheets on pharmaceutical processing aids	Peter Watts Philip Copestake Emma Russell Tanya Diver James Hopkins Anne Edwards
<b>Agrochemical sector</b>	
Preparation of dossiers for submission under 91/414/EEC, relating to the active substances of plant protection products. Assessment and review of complex, high-volume toxicity datasets	Peter Watts Christina Anderson Tanya Diver John Phillips
Preparation of dossiers for submission under 98/8/EC, relating to biocidal products. Assessment and review of complex, toxicity datasets and the preparation of data waivers	Philip Copestake Tanya Diver Peter Watts
A survey of Health Criteria Values underpinning the global regulatory limits on pesticides	Richard Young Peter Watts
Co-ordination of the EU-funded Concerted Action Projects instigated to construct EUROPOEM (European Predictive Operator Exposure Model) generic databases of operator, bystander and re-entry worker exposures to plant protection products and to develop predictive models	Peter Watts

## Government Agencies and International Organisations

<b>UK Environment Agency</b>	
<b>CLEA</b> Development of draft toxicity collations following the precepts outlined in SR2 (formerly CLR9) on about 30 environmental contaminants (or chemical classes). As a consequence, bibra has recently evaluated the toxicology of arsenic, cadmium, chromium, mercury, nickel, benzene, dioxins, and PAHs	James Hopkins Tanya Diver Peter Watts
<b>Benchmark dose analysis</b> Identification of key cancer data on selected soil contaminants in preparation for benchmark dose analyses  Estimation of BMDL <sub>10</sub> values of a laboratory animal carcinogen	James Hopkins
<b>Environmental Assessment Levels for Air</b> Assistance in the development of inhalation health criteria values on a number of atmospheric contaminants	James Hopkins Peter Watts

Project	Project Team
<b>Health Canada</b>	
<p><b>Categorization under the Canadian Environmental Protection Act (CEPA) 1999</b> Providing advice and critical comment on “Categorization of Organic Substances on the Domestic Substances List (DSL) for Inherent Toxicity to Humans: Proposed Initial Approach and Criteria” based on a processing of 100 compounds</p>	<p>James Hopkins Peter Watts Philip Copestake Christina Anderson Tanya Diver</p>
<p><b>Carcinogenicity and genotoxicity and CEPA: possible next steps</b> To consider how a categorization scheme or a prioritization process might be developed to reduce the number of compounds on the DSL that needed subsequent additional detailed phases of assessment based on an initial ranking as either carcinogens or genotoxins</p>	<p>James Hopkins</p>
<p><b>Polymers and CEPA: possible next steps</b> A consideration of how around 200 polymers might be prioritized for toxicity categorization under CEPA 1999</p>	<p>James Hopkins Peter Watts</p>
<p><b>The exposure response tool and some other CEPA issues</b> Consideration of the most cost-effective means to introduce a measure of dose-response for substances already identified as a problem by the Categorization process</p>	<p>James Hopkins Peter Watts</p>
<p><b>UVCBs and CEPA 1999</b> A consideration of the compositional issues related to a large list of UVCBs (Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials) and how these might be handled under CEPA 1999</p>	<p>James Hopkins Peter Watts Tanya Diver Philip Copestake Anne Edwards Emma Russell Christina Anderson</p>
<p><b>Thinking piece on petroleum UVCBs</b> Consideration of how the objectives outlined in CEPA 1999 might be achieved with respect to the petroleum products on the DSL</p>	<p>James Hopkins</p>
<p><b>Toxicity Profiles</b> Preparation of around 50 Toxicity Profiles for a subset of compounds (High or Intermediate Hazard, Greatest Potential for Human Exposure) on the “Maximal List“ of the DSL</p>	<p>James Hopkins Peter Watts Tanya Diver Anne Edwards Christina Anderson Philip Copestake Tracy Laughland</p>

<b>Project</b>	<b>Project Team</b>
<p><b>Comprehensive Hazard Reviews</b> Preparation of sections 8 (“Kinetics and Metabolism”), 9 (“Mammalian Toxicology”) and 10 (“Effects on Humans”) of Supporting Documentation for 19 Priority Substances under the CEPA 1999</p>	<p>James Hopkins Peter Watts Philip Copestake Christina Anderson Tanya Diver Tracy Laughland</p>
<p><b>Section 75 succinct summaries</b> Identification and summary of the main toxicological concerns that gave rise to the regulatory restrictions on 20 compounds banned or substantially restricted in OECD countries or elsewhere around the world</p>	<p>Tanya Diver James Hopkins</p>
<p><b>Screening assessments</b> Peer review of ten draft Screening Health Assessment Reports prepared by Health Canada</p>	<p>Philip Copestake Tanya Diver</p>
<p><b>Robust toxicity summaries</b> Preparation of robust summaries on perfluorooctylsulfonyl, perfluorobutylsulfonyl and perfluoroalkyl compounds</p>	<p>Christina Anderson Emma Russell Tanya Diver</p>
<p><b>State of Science (SOS) reports</b> Preparation of an SOS report from an existing generic SOS, together with updating from the published literature  Peer review of the draft of another SOS report</p>	<p>Anne Edwards Peter Watts</p>
<p><b>Fact sheets</b> Identification, summary and critical evaluation of the information on human, laboratory animal and <i>in vitro</i> studies of the toxic effects of 21 substances</p>	<p>Philip Copestake Peter Watts Tanya Diver</p>
<p><b>“Insufficient to conclude”</b> Peer review of a “Follow-up report on a PSL1 substance for which data were insufficient to conclude whether the substance was “Toxic” to human health: chlorinated paraffins”</p>	<p>Peter Watts</p>
<p><b>Peer review of hazard reports</b> Peer review of 33 hazard reports prepared by Health Canada</p>	<p>James Hopkins Peter Watts Tanya Diver</p>
<p><b>Hexachloroethane</b> Information and advice on the genotoxicity profile of hexachloroethane</p>	<p>Peter Watts Anne Edwards</p>
<p><b>(Q)SARs</b> Participation in a workshop on (quantitative) structure activity relationships (Q)SAR models and subsequent preliminary analyses of a range of analogue identification tools</p>	<p>Peter Watts</p>

<b>Project</b>	<b>Project Team</b>
<b>Peer consultation on genotoxicity</b> A contribution within a peer consultation on genotoxicity for categorization of “Inherent Toxicity” to humans	Peter Watts
<b>No-effect levels</b> Analysis of the variations between effect levels in comparable sub-chronic and chronic studies to determine what uncertainty factor should be applied in the development of tolerable intakes for “less than chronic” studies	Tanya Diver

<b>Organization for Economic Co-operation and Development (OECD)</b>	
The peer-review (under contract) of a large number of draft SIDS Initial Assessment Reports (SIARs) and draft SIDS Initial Assessment Profiles (SIAPs) prepared for discussion at the following SIDS Initial Assessment Meetings (SIAMs): 17, 18, 20-24 and 26-28	James Hopkins Philip Copestake Peter Watts Tanya Diver Anne Edwards Christina Anderson Emma Russell

<b>CEFIC (Confédération Européenne des Fédérations de l'Industrie Chimique)</b>	
Assistance in a RIP3.1 scoping project aimed at producing guidance for data requirements under REACH, including consideration of data sources, data quality, alternatives to study data and study waivers	Peter Watts Pat Aspin

<b>International Programme on Chemical Safety – World Health Organization</b>	
Preparation of nine CICADs (Concise International Chemical Assessment Documents) and attendance (as Temporary Advisors) in four FRB meetings	Peter Watts Philip Copestake
Peer-review of ten draft CICADs	Philip Copestake James Hopkins Peter Watts
The production of IPCS International Chemical Safety Cards (ICSCs), and participation in the Peer-Review Committee	Philip Copestake

<b>UK Ministry of Agriculture Fisheries and Food</b>	
Providing the UK MAFF with independent reviews, summaries of toxicology, and risk assessments of formulations submitted for approval as disinfectants under the 1981 Animal Health Act	Peter Watts

Project	Project Team
<b>UK Ministry of Agriculture Fisheries and Food / Department of Health</b>	
Preparation of MAFF/DoH literature reviews covering subjects including the toxicology of polychlorinated biphenyls (PCBs), the use of toxic equivalency factors for PCBs, and the pharmacokinetics of heavy metals in infants	Peter Watts Christina Anderson
<b>European Union - EUROPOEM projects</b>	
Co-ordination of the EU-funded Concerted Action Projects instigated to construct EUROPOEM (European Predictive Operator Exposure Model) generic databases of operator, bystander and re-entry worker exposures to plant protection products and to develop predictive models	Peter Watts
<b>Bibra – General</b>	
Preparation of close to 500 BIBRA Toxicity Profiles, concise hazard assessments, on important chemicals. Many of these were sponsored by member companies	Christina Anderson Philip Copestake Margaret Davies Tanya Diver Anne Edwards James Hopkins Tracy Laughland John Phillips Judy Ricketts Emma Russell Peter Watts Richard Young

## **bibra – toxicology advice & consulting**

### **– its evolution from BIBRA Information Services Ltd and Toxicology Advice & Consulting Ltd**

The British Industrial Biological Research Association (BIBRA) was founded in the early 1960s, jointly funded by industry and the UK government. Its objectives were to undertake basic and applied research in chemical toxicology, and to provide its member companies with information and advice on all aspects of chemical toxicology and the associated legislation.

Despite name changes, to BIBRA Toxicology International in 1989, and to BIBRA International in 1994, the Research Association constitution was maintained through to August 1999. At this point, BIBRA was bought by TNO, a Dutch contract research organization, and became a limited company, TNO BIBRA International Ltd. In November 2002, TNO sold the company to a private investor who traded up to the end of 2004 as BIBRA International Ltd.

The information and advisory business of BIBRA International Ltd was sold in January 2005 and it then traded as BIBRA Information Services Ltd (BIS). Its senior staff and owners are the toxicologists who provided the member company services of BIBRA (and BIBRA Toxicology International, BIBRA International, and TNO BIBRA International Ltd) through to the end of 2002. These toxicologists formed a consultancy company, Toxicology Advice & Consulting Ltd (TAC), in January 2003 and, since January 2005, TAC and BIS have operated jointly.

In 2007, BIS and TAC were amalgamated. The company is now known as:

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