

## **Bibra toxicology advice & consulting Ltd**

### **Corporate CV**

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

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 helpful to provide brief summaries of the various projects that **bibra** (in all its guises – see history on the final page), has worked on in the last 40+ years (although focusing on the more recent decade), along with the names of those scientists who worked on each project.

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



## Bibra toxicology advice & consulting Ltd

Bibra provides a comprehensive range of advisory and consultancy services on all aspects of chemical toxicological hazard and human health risk; bibra can also advise on associated legislation. The following examples illustrate the nature of some of the consultancy projects that we have undertaken.

### REACH

#### (Registration, Evaluation, Authorisation and Restriction of Chemicals)

Assistance on REACH registration tasks for hundreds of substances (including low- and high-tonnage, organic and inorganics, mono- and multi-constituent substances and UVCBs) including:

- Registration exemption advice (e.g. polymer definition)
- Searching both internal (e.g. TRACE) and external information sources for REACH-relevant data on toxicity, ecotoxicity, physicochemical properties and environmental fate
- TK/ADME assessment
- Categorisation and analysis of read-across possibilities, and robust justification for the use of read-across in line with ECHA's RAAF
- (Q)SAR analyses (and documentation)
- Data Gap Analysis (DGA), in readiness for generation of Integrated Testing Strategies (ITS) and drafting of data waivers
- Study commissioning at CROs
- Evaluating (e.g. for reliability) and summarizing papers/study reports, including preparation of (Robust) Study Summaries ((R)SS) and associated endpoint summaries in IUCLID
- Experience in the use of New Approach Methodologies (NAMs), including (Q)SAR, 'omics and in vitro methods, as part of a Weight-of-Evidence (WoE) approach for meeting REACH Standard Information Requirements (SIRs) without restoring to in vivo laboratory animal testing

Richard Young  
Chris Waine  
Peter Watts  
Daniel Threlfall  
Charles Johnson  
Beth O'Connell  
Craig Freeman  
Tanya Diver  
Anne Edwards  
James Hopkins  
Tracy Laughland

<ul style="list-style-type: none"> <li>• Consideration of endocrine disruption data, covering the four modalities (estrogenic, androgenic, thyroidal and steroidogenic)</li> <li>• DN(M)ELs (and qualitative), PNECs and PBT/vPvB assessment</li> <li>• Classification and labelling (to EU CLP)</li> <li>• Worker, consumer and general population exposure and risk assessment (e.g. calculation of RCRs, and documentation of appropriate RMMs and OCs)</li> <li>• Conduct of the Chemical Safety Assessment (CSA) and generation of the Chemical Safety Report (CSR), with or without Chesar</li> </ul>	
<p>Independent classification of many hundreds of substances used in consumer products, with regards to the criteria set-out in the GHS and the EU Classification, Labelling and Packaging (CLP; 1272/2008) regulations and associated guidance.</p> <p>Also, expert classification of mixtures in line with CLP (1272/2008).</p>	<p>Richard Young Chris Waine Peter Watts Daniel Threlfall Charles Johnson Beth O'Connell Tanya Diver Anne Edwards James Hopkins</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 format</p>	<p>Richard Young</p>
<p>Organising (Q)SAR analyses (e.g. DEREK, TOPKAT) to predict the toxicity of untested substances. Receiving the model outputs, searching more recent literature, producing accompanying reports and providing "sanity checks"</p>	<p>Richard Young Chris Waine Peter Watts Charles Johnson James Hopkins</p>
<p>Carrying out Q(SAR) analyses (alerts and profiles) on numerous substances, using the OECD Toolbox</p>	<p>Chris Waine Richard Young Charles Johnson Daniel Threlfall Beth O'Connell Peter Watts</p>
<p>Use of various tools (OECD Toolbox, ChemIDplus etc) to identify suitable read-across substances (structural analogues)</p>	<p>Chris Waine Richard Young</p>



	Charles Johnson Daniel Threlfall Beth O'Connell Peter Watts
Identification of CMRs, PBTs and vPvBs amongst a downstream user's large portfolio of supplied substances	Peter Watts
Responding to informal requests for more detail or clarification from ECHA and/or on receipt of a ECHA Evaluation draft decision following a Compliance Check or assessment of a testing proposal. This has included a case when the previously submitted dossier (>1000 tpa) produced by another consultancy was considered deficient in a number of areas (notably read-across approach and justification) and required significant updating and improvement (e.g. requirement for a pre-natal developmental toxicity study in a second species)	Richard Young Chris Waine Peter Watts
<b>Food and Consumer Products sector</b>	
Hazard and risk assessments relating to various 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	Tanya Diver James Hopkins Charles Johnson Chris Waine Peter Watts Richard Young
Urgent health risk assessments assisting in the crisis management of food contamination episodes	Beth O'Connell James Hopkins Peter Watts
Assessments of large number of ingredients (including CMRs), used in household consumer products. Including summaries of the critical toxicity data (concentrating on the inhalation and dermal routes), and also sections on existing Occupational Exposure Limits (OELs), exposure and use, classification and labelling, and existing Health Criteria Values (HCVs)	Beth O'Connell Tanya Diver Chris Waine Peter Watts Richard Young
Safety-in-use opinions (health risk assessments) on multi-component formulations, including food-contact inks,	Tanya Diver Anne Edwards



adhesives, cold seals, food-contact matrices and fruit labels	James Hopkins Tracy Laughland Peter Watts Richard Young
Preparation of succinct overviews on the occurrence, intake and toxicology of various food and drink contaminants (synthetic and natural)	Tanya Diver Anne Edwards James Hopkins Beth O'Connell Charles Johnson Tracy Laughland Daniel Threlfall Peter Watts Richard Young
Urgent hazard and risk assessment on a surface contaminant of a consumer product likely to make contact with human skin	James Hopkins Peter Watts
Health 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
Secondment of bibra toxicologists to assist a member company during the introduction of an SAP Product Lifecycle Management (PLM) system, notably the conduct of hazard and risk assessments for ingredients in a range of consumer products	Richard Young Phil Copestake
Critical summaries of the toxicological status of food additives	Tanya Diver Anne Edwards James Hopkins Peter Watts Richard Young Tracy Laughland
Hazard assessments of a wide range of plant-derived extracts with potential use as nutraceuticals	Tanya Diver Anne Edwards James Hopkins Peter Watts Richard Young



Hazard and risk assessments related to probiotics intended for food use	Peter Watts
Summaries of toxicity data, with an emphasis on carcinogenicity, mutagenicity and reproductive toxicity, on several hundred flavourings and fragrances used in various consumer products	Tanya Diver Anne Edwards James Hopkins Beth O'Connell Daniel Threlfall Chris Waine Peter Watts Richard Young Tracy Laughland Helen Hunt Kelly Jackson
Preparation and/or updating of toxicity reviews, in client-approved formats, on dozens of chemicals in preparation for disclosure to different national regulatory agencies	Tanya Diver Anne Edwards Charles Johnson Beth O'Connell Peter Watts Richard Young Helen Hunt Kelly Jackson Tracy Laughland
Preparation of several hazard reports on a major consumer substance. Using the published literature to generate reports on general systemic toxicity, cardiovascular, reproductive and developmental effects, and co-carcinogenicity studies	Peter Watts Tanya Diver Tracy Laughland
Critical review of the literature on the role and value of currently used genotoxicity screening tests to predict mammalian carcinogenicity	James Hopkins Tanya Diver
Reviews of the literature on the skin absorption of heavy metals, such as antimony, arsenic, cadmium, lead and mercury	James Hopkins Anne Edwards
Classification of over 500 ingredients of consumer products by the Cramer, Ford and Hall (1978) decision tree and by Toxtree	Peter Watts



Application and evaluation of structure-activity relationship (SAR) methodology	Beth O'Connell Anne Edwards Peter Watts James Hopkins Tanya Diver
Critical evaluation of the neurobehavioural toxicology of a food additive class	Tanya Diver James Hopkins
Comparison of the toxicity profiles of two salts of a metal, to assist in reaching a substitution decision	Anne Edwards Peter Watts
Critical evaluation of the literature relating to ethanol absorption from various types of alcoholic beverage	Peter Watts
Data mining of the published literature for toxicity data suitable for benchmark dose modelling, to allow margins of exposure to be estimated	Anne Edwards Beth O'Connell Richard Young
Health risk assessments of various cigarette filters	Tanya Diver James Hopkins Peter Watts
Tabulation of ADIs for several hundred flavourings	Beth O'Connell Richard Young
Consumer health risk assessment of a precipitate in a breath spray	Beth O'Connell Peter Watts
Consumer health risk assessments of various ingredients in tooth-whitening products	James Hopkins Charles Johnson Beth O'Connell Peter Watts
Compiling a Cosmetic Product Safety Report (CPSR) assessing the safety of a skin cream. Included a CSA	Beth O'Connell Peter Watts Richard Young
Overview of the prevalence of sensory hyperreactivity, chemical sensitivity and food allergy in the general population	Tanya Diver James Hopkins
Review on the value of the Direct Peptide Reactivity Assay (DPRA) for identifying skin and/or respiratory sensitisers	Beth O'Connell
Review on the use of the mouse Local Lymph Node Assay (LLNA) for identifying skin sensitisers, and the human health implications of a positive result	Tanya Diver James Hopkins



<b>Chemicals sector</b>	
An elucidation of the Mode of Action (MoA) of carcinogenic and toxic constituents of complex mixtures using the precepts of the Human Relevance Framework of the International Programme on Chemical Safety (IPCS)	James Hopkins Beth O'Connell Peter Watts
REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)  Assistance on REACH Registration and Evaluation tasks for a large 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 authorisations under the Biocidal Products Directive (BPD) and Biocidal Products Regulation (BPR)	Tanya Diver Anne Edwards Richard Young Peter Watts
Assistance with Pre-Manufacture Notice (PMN) submission, as a Support Registrant, for compliance with the US Toxic Substances Control Act (TSCA)	Beth O'Connell Richard Young
Hazard and risk assessments on chemicals encountered in the workplace	Tanya Diver Anne Edwards James Hopkins Tracy Laughland Peter Watts Richard Young
Hazard and risk assessment of low-dose exposures experienced by the general population as a result of industrial emissions	James Hopkins Peter Watts
Derivation of proposed Workplace Exposure Limits (WELs) 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	James Hopkins 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	James Hopkins Peter Watts





Preparation of “position papers” on important chemicals of high concern that have found their way into various environmental media e.g. POP chemicals	Peter Watts Richard Young
Providing regular literature monitoring searches on chemicals or chemical groups e.g. plasticisers, oxygenated solvents, identifying the key toxicological data, and preparing evaluative summaries	Tanya Diver Beth O’Connell Helen Gregory Tracy Laughland
Preparation of a FOCS report for a major European sector	Peter Watts
Health risk assessments of the general population exposure to tracers and/or their degradation products due to use in domestic and industrial fuels	James Hopkins Peter Watts Richard Young
<b>Pharmaceuticals sector</b>	
Setting of Permitted Daily Exposures (PDEs) for numerous compounds found as extractables and/or anticipated to be potential leachables in drug products	Peter Watts James Hopkins Beth O’Connell Daniel Threlfall Charles Johnson
Setting PDEs for contamination of active pharmaceutical substances by unrelated actives previously manufactured at the same facility	Peter Watts James Hopkins Anne Edwards
Recommending Occupational Exposure Levels (OELs, OESs) for pharmaceutical actives	Peter Watts James Hopkins Beth O’Connell
Revising and updating an Investigational Brochure (IB), to be submitted to the US FDA and used by clinicians, setting out the key pharmacological and toxicological issues concerning oral administration of cannabidiol (CBD) to patients	Richard Young Pete Watts Kelly Jackson
A large number of hazard reviews and toxicological risk assessments on low-level pharmaceutical impurities (including genotoxic impurities) and degradation products in pharma products (including parenteral nutrition products)	James Hopkins Charles Johnson Chris Waine Peter Watts Daniel Threlfall Richard Young Beth O’Connell
Including assessment in line with ICH M7 guidance on DNA-reactive (mutagenic) impurities	Richard Young Beth O’Connell
Expert determination of the likely mutagenicity status of numerous pharmaceutical process impurities, in line with	Charles Johnson Chris Waine



M7 guidance. Use of Leadscope M7 modules (expert alert and statistical based), accompanied by expert reviews	Peter Watts Daniel Threlfall
Hazard reviews and risk assessments on excipients and contaminants in pharmaceutical products (including parenteral nutrition products)	James Hopkins Peter Watts Richard Young
For due diligence purposes, hazard assessment of a pharmaceutical active ingredient	James Hopkins
Toxicity reviews of the non-clinical toxicology of pharmaceutical actives	James Hopkins Charles Johnson Peter Watts Richard Young
A number of reviews of the toxicological implications arising from a change in the counter-ion in various ionic pharmaceutical actives	James Hopkins Peter Watts Richard Young
Comprehensive literature searches for toxicity data on impurities of well-known pharmaceutical actives	Chris Waine James Hopkins Beth O'Connell Daniel Threlfall Peter Watts Richard Young Tanya Diver
Numerous hazard and risk assessments relating to extractables and leachables from processing equipment, packaging materials, container-closure systems (CCSs), etc into simulating solvents and pharmaceutical products	Tanya Diver James Hopkins Beth O'Connell Charles Johnson Daniel Threlfall Chris Waine Peter Watts
Provision of advice on which key extractables should be analysed in subsequent leachable studies	Chris Waine Peter Watts James Hopkins Charles Johnson Daniel Threlfall
Setting of Analytical Evaluation Thresholds (AET), Safety Concern Thresholds (SCT), and Qualification Thresholds (QT) for application to leachables, following extractables studies	Charles Johnson Dan Threlfall Chris Waine Peter Watts



Safety-in-use opinions on pharmaceutical formulations applied regularly to the skin	Tanya Diver James Hopkins Peter Watts Richard Young
<b>Medical devices sector</b>	
Expert panel member of the British (BSI CH/194) and International (ISO TC/194) Technical Committees responsible for the standards relating to the biological and clinical evaluation of medical devices. These include the ISO 10993 series and ISO TS/21726	Chris Waine
Biological safety assessments of numerous medical devices, in line with the principles of ISO 10993 and FDA's 2016 guidance for industry and FDA staff. Including wound dressings, surgical instruments, permanent implants, wipes, ointments, other medical equipment, etc	Beth O'Connell Charles Johnson Daniel Threlfall Pete Watts James Hopkins
Advice on ISO 10993 classification and selection of tests	Beth O'Connell Charles Johnson Daniel Threlfall Pete Watts James Hopkins
Biocompatibility assessments for many medical devices. Review and interpretation of CRO biocompatibility tests	Beth O'Connell Charles Johnson Daniel Threlfall Pete Watts James Hopkins
Literature reviews of key biocompatibility endpoints e.g. to waive new testing and/or add to existing data to create a WoE assessment	Beth O'Connell Charles Johnson Daniel Threlfall Pete Watts James Hopkins
ISO 10993-17 Toxicological Risk Assessments (TRAs) of extractables identified in analytical studies e.g. extractables studies compliant with ISO 10993-18. Using these studies to address complex biocompatibility endpoints e.g. subchronic toxicity, chronic toxicity, reproductive and developmental toxicity, carcinogenicity and genotoxicity	Beth O'Connell Charles Johnson Daniel Threlfall Pete Watts James Hopkins Helen Gregory Craig Freeman



	Jessica Gagalang Helen Hunt Kelly Jackson
Drafting of documents justifying extension of contact time for medical devices in accordance with the requirements of ISO 10993-1	Chris Waine Peter Watts Richard Young
Risk assessments relating to changes in medical films as a result of suppliers altering their manufacturing processes	Peter Watts
Bridging reports for medical devices. Read-across of biocompatibility studies between similar dressings	Peter Watts Beth O'Connell
Setting of PDEs for silver in silver-based wound dressings	Charles Johnson Beth O'Connell James Hopkins Peter Watts
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>Electronic cigarette and nicotine sector</b>	
Assisting clients with the preparation of regulatory data packages for their e-cigarette products, including e-liquids, bottles, and devices. Notably, companies Tobacco Products Directive (TPD) notifications to the relevant EU Member State Competent Authorities (MSCAs) and Pre-Market Tobacco Applications (PMTAs) submitted to the US FDA. This work included production of 100s of toxicity profiles (focusing on CMR, sensitisation, cardiovascular, and addictiveness properties) for e-liquid ingredients. Toxicity profiles were also prepared for 100s of extractables and leachables from the bottles/devices, and also target and non-targeted analytes in the emissions (including thermal degradation products). For many, the work extended to consumer risk assessment of the ingredients, leachables, and emission analytes	Richard Young Charles Johnson Beth O'Connell Peter Watts
Evaluation of flavourings used e-liquids, focusing on the inhalation route of exposure. Use of read-across and (Q)SAR in the absence of substance-specific data. Also identification of existing HCVs and, in the absence of recent, reliable, inhalation values, the proposal of suitable	Richard Young Charles Johnson Beth O'Connell Peter Watts Daniel Threlfall



benchmarks for future inhalation risk assessments for consumers	
Health risk assessments of complex flavouring mixtures for addition to e-cigarette formulations	Peter Watts Richard Young
Health risk assessment of low molecular weight aldehydes (e.g. formaldehyde and acrolein) analytically determined (identified and quantified) in e-cigarette emissions	Richard Young Charles Johnson Peter Watts
Health risk assessments based on extractables and headspace studies of an array of components of e-cigarette devices	Charles Johnson Daniel Threlfall Pete Watts
Advice on extractables that are likely health-critical for targeting in subsequent leachables studies on e-cigarette devices and components	Charles Johnson Pete Watts
Health risk assessments based on leachables studies on e-cigarette devices	Charles Johnson Daniel Threlfall Pete Watts
Provision of hazard assessments for several flavourings intended for use in e-cigarettes, including ADME insights to allow extrapolation from the oral laboratory animal data to the intended inhalation consumer exposure	Richard Young Beth O'Connell Charles Johnson Daniel Threlfall Peter Watts
Health risk assessment for bystanders potentially exposed to chemicals released from e-cigarettes	Peter Watts
Assessment of the potential health impact of increasing the weight of e-cigarette components made of a specific polymeric material, based on extractable study results	Peter Watts
Comprehensive assessment of the toxicity data on nicotine, and also of various nicotine salts (nicotine benzoate)	Richard Young Peter Watts Anne Edwards Chris Waine
Toxicity review of Heated Tobacco Products (HTPs), also known as heat-not-burn products (which warm tobacco, rather than combust it)	Richard Young Pete Watts



<b>Plant Protection Products (PPPs), Biocides and veterinary medicines sector</b>	
Assessment of the endocrine disruption properties of active substances according to 2017/2100 for biocides and 2018/605 for plant protection products, following the ECHA/EFSA guidance (2018) and including production of the Appendix E1 Excel spreadsheet	Anne Edwards Helen Gregory
Preparation of dossiers for submission under 91/414/EEC, relating to the active substances of PPPs. Assessment and review of complex, high-volume toxicity datasets	Peter Watts Tanya Diver
Preparation of dossiers for submission under 98/8/EC and (EU) 528/2012, relating to biocidal products. Assessment and review of complex, toxicity datasets and the preparation of data waivers	Chris Waine Daniel Threlfall Tanya Diver Peter Watts
Literature searches and subsequent refining and study summary preparation to assist in the preparation of Literature Review Reports (LRRs), following EFSA guidance, for updating dossiers on PPP actives (under 1107/2009)	Anne Edwards Beth O'Connell Peter Watts
Expert derivations of classification proposals for biocide product families (in line with EU CLP) based on the full compositions - active substances and excipients	Charles Johnson Chris Waine Daniel Threlfall Peter Watts
A survey of HCVs underpinning the global regulatory limits on several hundred pesticides/crop protection agents	Tanya Diver Anne Edwards Beth O'Connell Peter Watts Richard Young
Consultancy on the relevance of a positive genotoxicity study on an active substance. Assessment of WoE and the influence of administration route	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
Preparation of an urgent expert opinion on the dermal absorption of a PPP active ingredient	Daniel Threlfall Peter Watts
Update of a health risk assessment report and certain sections (Part III) of a veterinary product to support an application for over-the-counter sale	James Hopkins Daniel Threlfall



<p>Health risk assessments of extractables in veterinary products intended for use in dogs, cattle and sheep. Included dermal and injection products</p>	<p>Peter Watts Charles Johnson Daniel Threlfall</p>
<p><b>Government Agencies and International Organisations</b></p>	
<p><b>UK Environment Agency</b></p>	
<p><b>Contaminated land</b></p> <p>Development of toxicity collations using the principles outlined in SR2 (formerly CLR9) as part of the Contaminated Land Exposure Assessment (CLEA). As a consequence, bibra has evaluated the mammalian toxicology of a large number of substances culminating in reports that recommend oral and inhalation health criteria values. Reports on the following chemicals have been published: benzene; toluene; ethylbenzene; xylenes; mercury; selenium; arsenic; nickel; cadmium; phenol; dioxins, furans and dioxin-like PCBs. These can be found on the EA's website (<a href="http://www.environment-agency.gov.uk/research/planning/64002.aspx">http://www.environment-agency.gov.uk/research/planning/64002.aspx</a>). Draft reports have also been prepared on: chromium; cyanide (inorganic); lead (inorganic); lead (organic); polycyclic aromatic hydrocarbons</p>	<p>James Hopkins Peter Watts</p>
<p><b>Contaminated air</b></p> <p>Based on an assessment and distillation of the conclusions of authoritative reviews produced by national and international organizations, together with an evaluation of the impact of more recent primary literature, draft reports have been prepared on acrylonitrile, antimony, carbon tetrachloride, chloromethane, dimethyl formamide, hydrogen cyanide, phenol, selenium, tetrachloroethane, trichloroethylene and vinyl chloride. The objective is the derivation of Tolerable Concentrations in Air (TCA). The finalized reports will ultimately feed into the derivation and adoption of an Environmental Assessment Level (EAL) for use within the Environmental Permitting Regulations</p>	<p>James Hopkins Peter Watts Beth O'Connell</p>
<p><b>Benchmark dose analysis</b></p> <p>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</p>	<p>Anne Edwards James Hopkins Richard Young</p>



<b>Health Canada</b>	
<p><b>Categorization under the Canadian Environmental Protection Act (CEPA) 1999</b></p> <p>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>Tanya Diver James Hopkins Peter Watts</p>
<p><b>Carcinogenicity and genotoxicity and CEPA: possible next steps</b></p> <p>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></p> <p>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></p> <p>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></p> <p>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>Tanya Diver Anne Edwards James Hopkins Peter Watts</p>
<p><b>Thinking piece on petroleum UVCBs</b></p> <p>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></p>	<p>James Hopkins Peter Watts</p>





Preparation of around 75 Toxicity Profiles for a subset of compounds (High or Intermediate Hazard, Greatest Potential for Human Exposure) on the “Maximal List” of the DSL	Tanya Diver Anne Edwards Tracy Laughland
<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	James Hopkins Peter Watts Tanya Diver Tracy Laughland
<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	Tanya Diver James Hopkins
<b>Screening assessments</b> Peer review of ten draft Screening Health Assessment Reports prepared by Health Canada	Tanya Diver
<b>Robust toxicity summaries</b> Preparation of robust summaries on perfluorooctylsulfonyl, perfluorobutylsulfonyl and perfluoroalkyl compounds (PFOS, PFBS and PFOA)	Tanya Diver
<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	Anne Edwards Peter Watts
<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	Tanya Diver Peter Watts
<b>“Insufficient to conclude”</b> Peer review of a “Follow-up report on a PSLI substance for which data were insufficient to conclude whether the substance was “Toxic” to human health: chlorinated paraffins”	Peter Watts
<b>Peer review of hazard reports</b> Peer review of 33 hazard reports prepared by Health Canada	Tanya Diver James Hopkins Peter Watts

<p><b>Hexachloroethane</b></p> <p>Information and advice on the genotoxicity profile of hexachloroethane</p>	<p>Anne Edwards</p> <p>Peter Watts</p>
<p><b>(Q)SARs</b></p> <p>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>
<p><b>Peer consultation on genotoxicity</b></p> <p>A contribution within a peer consultation on genotoxicity for categorization of “Inherent Toxicity” to humans</p>	<p>Peter Watts</p>
<p><b>No-effect levels</b></p> <p>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</p>	<p>Tanya Diver</p>
<p><b>Organization for Economic Co-operation and Development (OECD)</b></p>	
<p>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, 26-29 and 31, and Cooperative Chemicals Assessment Meetings (CoCAMs) 1 and 2</p>	<p>James Hopkins</p> <p>Peter Watts</p> <p>Tanya Diver</p> <p>Anne Edwards</p>
<p><b>CEFIC (Confédération Européenne des Fédérations de l'Industrie Chimique)</b></p>	
<p>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</p>	<p>Peter Watts</p>
<p><b>International Programme on Chemical Safety – World Health Organization</b></p>	
<p>Preparation of nine CICADs (Concise International Chemical Assessment Documents) and attendance (as Temporary Advisors) at four FRB meetings</p>	<p>Peter Watts</p>
<p>Peer-review of ten draft CICADs</p>	<p>James Hopkins</p> <p>Peter Watts</p>
<p>The production of IPCS International Chemical Safety Cards (ICSCs), and participation in the Peer-Review Committee</p>	<p>James Hopkins</p> <p>Peter Watts</p> <p>Philip Copestake</p>



<b>IRSSST (Institut de recherche Robert-Sauvé en santé et en sécurité du travail)</b>	
A review of selected literature (1995–2009) on the carcinogenicity of trichloroethylene (TCE). Published 2010	Peter Watts
<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
<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
<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	Tanya Diver Anne Edwards James Hopkins Peter Watts Richard Young Tracy Laughland

## **Our 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 Bibra toxicology advice & consulting Ltd.