WORKSHOP PROGRAMME

Chemical Respiratory Allergy: Clinical Information and How to Use it and Improve it

27th and 28th October 2016

NH Nacional Hotel
Madrid, Spain

Organised by:

European Centre for Ecotoxicology and Toxicology of Chemicals
AIMS OF THE WORKSHOP

Specific Objectives:

1. Develop best practice guidance on how to assess and use available human data for the identification and regulation of respiratory sensitzers, including the creation of a framework for the interpretation of strength of evidence and weighting.

2. Explore opportunities to identify biomarkers for sensitisation to chemical respiratory allergens – and the use of such biomarkers for prospective monitoring of workforces to more accurately identify threshold data.

Output

1. Define and promote a consistent, best practice, strategy for the evaluation of available human data for respiratory sensitzers, for use by regulators in formal decision-making processes.

2. Publish a consensus opinion on the research required for the identification of human biomarkers of chemical respiratory sensitisation, and application in prospective monitoring of workforces with the ultimate aim of refining current human threshold data to reduce uncertainty in current risk assessment approaches.
# Programme for Session I: Guidance Development

### 27 October  Day 1 (Modigliani room)

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker/Group</th>
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<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registration</td>
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<tr>
<td>09:00-09:15</td>
<td>Introduction, Aims &amp; Objectives, Plan for the 2 days</td>
<td>Stella Cochrane Unilever, UK</td>
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<tr>
<td>09:15-09:50</td>
<td>Chemical Respiratory Allergy: definitions, mechanisms, hazard identification and characterisation</td>
<td>Ian Kimber Manchester University, UK</td>
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<tr>
<td>09:50-10:20</td>
<td>The Case of ADCA – A chemical sensitizer?</td>
<td>Axel Schnuch University of Gottingen, DE</td>
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<tr>
<td>10:20-11:00</td>
<td>Coffee break (Hall Atocha)</td>
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<tr>
<td>11:00-11:30</td>
<td>Current status of regulation of respiratory sensitizers</td>
<td>Josje Arts AkzoNobel, NL</td>
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<tr>
<td>11:30-12:00</td>
<td>Clinical Diagnosis of Occupational Asthma – practice and challenges/opportunities</td>
<td>Paul Cullinan Imperial College, UK</td>
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<tr>
<td>12:00-12:30</td>
<td>Moving beyond hazard identification towards hazard characterization: illustrated with case studies</td>
<td>David Basketter DABMEB Consult, UK</td>
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<tr>
<td>12:30-13:30</td>
<td>Lunch (Restaurante Nacional)</td>
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<tr>
<td>13:30-14:30</td>
<td>Panel Discussion + Q&amp;A with morning speakers: setting the scene for the Round Table Discussions to follow</td>
<td>All speakers (above) Moderator: Alan Poole</td>
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<tr>
<td>14:30-14:40</td>
<td>Details for Round Table Discussions</td>
<td>Madeleine Laffont</td>
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| 14:40-15:40 | Round Table Discussions (held in parallel):

1. What are the criteria for data admissibility and weighting for classification?

   **Green Group** (Modigliani room)
   **Chair:** David Basketter
   **Rapporteur:** Danielle Botelho

   Possible Questions to prompt – but not constrain discussion:
   - Should evidence of an immunological mechanism be required to classify a substance as a sensitizer?
   - How much is enough? What are the quantitative and qualitative classification criteria to label a substance as a sensitizer?
   - What should be the minimum reporting requirements for chemical evidence of sensitization?

2. The identification of biomarkers for chemical respiratory allergens and for sensitization of the respiratory tract?

   **Blue Group** (Picasso room)
   **Chair:** Ian Kimber
   **Rapporteur:** Stella Cochrane

   Possible Questions to prompt – but not constrain discussion:
   - What are the most appropriate potential immunological biomarkers?
   - Are there potentially relevant non-immunological biomarkers?
   - Are there lessons to be learned from skin sensitization?
   - Are there lessons to be learned from respiratory allergy to proteins?

<p>| 15:40-16:15 | Coffee break (Hall Atocha) |</p>
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Chair &amp; Rapporteur from each Roundtable</th>
</tr>
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<tbody>
<tr>
<td>16:15-17:00</td>
<td>Plenary &amp; reporting back</td>
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<tr>
<td>17:00-17:20</td>
<td>Conclusions &amp; details for tomorrow</td>
<td>Stella Cochrane Unilever, Danielle Botelho RIFM, USA</td>
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<tr>
<td>17:20-17:30</td>
<td>Details for Museum visit &amp; dinner</td>
<td>Madeleine Laffont ECETOC</td>
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<td>18:45-20.00</td>
<td>Reina Sofia Museum Visit</td>
<td>All</td>
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<td>20:00</td>
<td>Dinner: Rest. Arzabal (Museum, Sabatini building)</td>
<td>All</td>
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**Museo Nacional Centro de Arte Reina Sofía**
Calle de Santa Isabel, 52
28012 Madrid
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Chair(s)</th>
<th>Rapporteur(s)</th>
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<tbody>
<tr>
<td>08:45-09:00</td>
<td>Welcome and proceedings</td>
<td>Ian Kimber</td>
<td>Manchester University, UK</td>
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<tr>
<td>09:00-10:15</td>
<td>Roundtable Discussion 3: Assessment of Sensitising potential - Relevance for classification and SVHC</td>
<td>All participants</td>
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<td></td>
<td>David Basketter and Ian Kimber</td>
<td>Danielle Botelho and Stella Cochrane</td>
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<td></td>
<td><strong>Chairs:</strong> David Basketter and Ian Kimber</td>
<td><strong>Rapporteurs:</strong> Danielle Botelho and Stella Cochrane</td>
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<td><strong>Possible Questions to prompt – but not constrain discussion:</strong></td>
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<td>- Is it necessary for the substance to provoke allergic symptoms <em>(e.g. during a provocation test)</em> in order to be eligible for classification – or is it sufficient that it provokes a biological response <em>(e.g. antibodies)</em> in the absence of clinical symptoms?</td>
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<td>- How can we ensure that biomarkers are adequately specific and sensitive?</td>
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<td>10:15-10:45</td>
<td>Coffee break (Atocha Hall)</td>
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<tr>
<td>10:45-11:30</td>
<td>Plenary &amp; Discussion</td>
<td>Chairs &amp; Rapporteurs</td>
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<tr>
<td>11:30-13:00</td>
<td>Drafting: 1. Describe steps required to identify biomarkers for sensitization to chemical respiratory allergens – and their use for prospective monitoring of workforces to more accurately identify threshold data</td>
<td>All Chair: I. Kimber Rap: S. Cochrane</td>
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<tr>
<td>13:00-14:00</td>
<td>Lunch (Restaurante Nacional)</td>
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<tr>
<td>14:00-15:30</td>
<td>Drafting: 2. Guidance on how to assess and use available human data for the identification and regulation of respiratory sensitizers (include interpretation of strength of evidence and weighting)</td>
<td>All Chair: D. Basketter Rap: D. Botelho</td>
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<tr>
<td>15:30-16:00</td>
<td>Conclusions, Wrap Up and Close</td>
<td>Ian Kimber</td>
<td>Manchester University, UK</td>
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<tr>
<td>16:00-16:30</td>
<td>Closing Coffee break (Atocha Hall)</td>
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VENUE

**Hotel NH Nacional**
Paseo del Prado 48
28014 Madrid
Spain

Tel.: +34 91 4296629

**Location:**
- Madrid city centre
- 15.55 km Adolfo Suárez Madrid–Barajas Airport
- 5.41 km Chamartin Station
- 0.59 km Atocha Station
Chemical Respiratory Allergy: Clinical Information and How to Use it and Improve it

27-28 October, 2016
Madrid

<table>
<thead>
<tr>
<th>First name</th>
<th>Name</th>
<th>Affiliation</th>
<th>E-mail</th>
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<tbody>
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<td>Arts</td>
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<td>Procter and Gamble, USA</td>
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<td>Munich Technical University, DE</td>
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<td>University of Utrecht, NL</td>
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<td>Kimber</td>
<td>University of Manchester, UK</td>
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<tr>
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## Roundtables Groups

<table>
<thead>
<tr>
<th>GREEN GROUP</th>
<th>BLUE GROUP</th>
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<tbody>
<tr>
<td><strong>Modigliani room</strong></td>
<td><strong>Picasso room</strong></td>
</tr>
<tr>
<td>Danielle Botelho, RIFM, USA <em>(R 1)</em></td>
<td>Stella Cochrane, Unilever, UK <em>(R 2)</em></td>
</tr>
<tr>
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<td>Frank Gerberick, Procter and Gamble, USA</td>
</tr>
<tr>
<td>David Basketter, DABMEB Consult, UK <em>(Chair 1)</em></td>
<td>Dick Heederik, University of Utrecht, NL</td>
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<tr>
<td>Paul Cullinan, Imperial College, UK</td>
<td>Ian Kimber, University of Manchester, UK <em>(Chair 2)</em></td>
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Dr. Stella Cochrane
Scientist: Allergy and Immunology
Unilever

Dr Cochrane joined Unilever’s Safety and Environmental Assurance Centre in 2004 after working in the University of Southampton’s Department of Infection and Inflammation Research, where her research focussed on the biochemistry and immunology of food allergy.

Dr Cochrane now provides scientific expertise and guidance in immunotoxicology and risk assessment, principally in the area of IgE-mediated allergies, covering both food (risk assessment of novel proteins and allergen risk management in manufacturing facilities) and home and personal care products.
Chemical Respiratory Allergy: Definitions, Mechanisms, Hazard Identification and Characterisation
Professor Ian Kimber
Professor of Toxicology
Faculty of Biology, Medicine and Health,
University of Manchester, UK

Allergic sensitisation of the respiratory tract by chemicals poses a number of toxicological challenges, and there remain many controversies. These include, importantly, the mechanisms through which sensitisation is acquired (including particularly the role of IgE antibody), and the relevance of the skin for driving sensitisation. These uncertainties will be considered here, as will their impact on approaches for hazard identification and characterisation.

In addition, this presentation will seek to provide a working definition of chemical respiratory allergy, and will review briefly a recently published Adverse Outcome Pathway that explores the key events resulting in sensitisation of the respiratory tract.
Professor Ian Kimber
Professor of Toxicology
Faculty of Biology, Medicine and Health,
University of Manchester, UK

Ian Kimber is currently Professor of Toxicology and Associate Dean for Business Development in the Faculty of Life Sciences at the University of Manchester.

He has broad research interests at the interface between toxicology and immunology, with a particular focus on allergy and inflammation.

Professor Kimber holds, and has held, a variety of positions on national and international expert and scientific advisory committees. Currently these include the following: Member UK Medicines and Healthcare products Regulatory Agency (MHRA) Devices Expert Advisory Committee, Programme Advisor Food Standards Agency Food Allergy and Intolerance Research Programme, member Scientific Advisory Board National Institute for Biological Standards and Control, and member MRC Translational Research Group. Professor Kimber was previously President of the British Toxicology Society (2012-2014), and Chairman of the Board of the UK National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) (2008-2013).

He has published over 530 peer-reviewed research papers and review articles, over 100 book chapters, and 6 books. He serves currently on the editorial boards of toxicology, immunology, dermatology and pathology journals.

Professor Kimber has received a number of awards and prizes. These include: the SmithKline Beecham Laboratory Animal Welfare Prize (2000) (jointly with David Basketter and Frank Gerberick), the 9th Robert A Scala Award in Toxicology (2001), the Doerenkamp-Zbinden Foundation Prize for Realistic Animal Protection in Biomedical Research (2001), Society of Toxicology Enhancement of Animal Welfare Award (2003) (jointly with Frank Gerberick), and Society of Toxicology Immunotoxicology Career Achievement Award (2005).

In 2010 Professor Kimber received the Eurotox Bo Holmstedt Memorial Fellowship Award and Lecture at the International Congress of Toxicology.

In 2015 Professor Kimber received the Society of Toxicology Distinguished Toxicology Scholar Award.

In 2015 he was awarded the Barnes Prize Lecture by the British Toxicology Society.

Professor Kimber was elected to membership of Academia Europaea.

In 2011 Professor Kimber was awarded an OBE in the Queen’s Birthday Honours list for services to science.
The case of ADCA – a chemical sensitiser?

H. Lessmann, A. Schnuch

University of Göttingen/Germany

Azodicarbonamide (ADCA) is used as a foaming agent in the production of a number of different products (e.g. wallpapers, undercoatings for cars, various building materials). In the 70ties and 80ties there were some reports on respiratory symptoms suspected to be related to exposure to ADCA.

Data of different sources, all from the 70ties and 80ties, with decreasing evidence, may support the notion of ADCA being a respiratory allergen: 1. Well documented reports on 3 cases from two centers. 2. Less well documented reports on 8 cases from three centers. 3. “Epidemiological” studies on exposure measurements and on workers with respiratory symptoms from three plants manufacturing or using ADCA. 4. Notification of suspected, yet not diagnosed cases to registers of occupational health (e.g. SWORD).

Evidence:
There are at most 3 reasonable cases in which pulmonary reactions have been verified in sufficiently documented provocation tests (1x Korea, 2x Canada). In spite of some shortages, these 2 case reports give some evidence for an immunological mechanism and could therefore be regarded as sufficient to fulfill the criteria for marking ADCA with „Sa“ (sensitising airways), although additional immunological evidence like positive prick tests or proof of specific IgE is lacking.

Shortcomings and unanswered questions:
- The identity of the ADCA as used in provocation tests is not documented in any case report!
- No allergological diagnostics have been done in epidemiological studies from the working place and no such information is available for cases from registration systems
- Unlike other low-molecular weight allergens, ADCA is negative in the Local Lymph Node Assay
- Considerations on the reactivity of ADCA and its metabolites do not point to a stable protein binding (necessary for sensitisation)
- The fine dust particles, possibly in combination with other factors (especially in the plastics industry) may also be causative
- The impact of decomposition products has not been evaluated in the plastics industry
- Further exposure scenarios may be involved, regarding information from some patent literature (e.g. the possible role of admixtures like carbonic anhydrides)
- Regarding the (former) relatively wide distribution/exposure (ten thousands of workers exposed per year), the only 3 well documented cases provide little evidence for a relevant sensitising potential

Conclusion:
A respiratory sensitising effect of azodicarbonamide is not sufficiently proven and the substance has therefore not been marked with „Sa“.
Prof. Dr. med. Axel Schnuch  
Physician (Dermatology and Allergology)  
Chairman of the IVDK Institute at  
the Georg-August-Universitaet Goettingen

Resident in dermatology (University of Goettingen).  1982-1987  
Senior registrar in dermatology and allergology (University of Goettingen)  1987-1993  
Chairman of the IVDK (Information Network of Departments of Dermatology)  1989-  
“Habilitation” (”Privatdozent) University of Goettingen  2000  
“Professor Dr. med” University of Göttingen  2005  

Main activities/ research  
Clinical epidemiology and surveillance of contact allergies  
Occupational health with focus on allergies  
Genetics and polymorphisms in contact allergy  
Unwanted side effect of drugs  

Commissions  
Full member of the Drug Commission of the German Medical Association  (Arzneimittelkommission der Deutschen Aerzteschaft), Cologne/Berlin  1994 -  
Full member of the Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area of the Deutsche Forschungsgemeinschaft („MAK Kommission der DFG“) and Chairman of the Sub-Commission „Skin and Allergy“, Berlin  1998 -  
Member of the Drug Safety Commission of the Federal Institute for Drugs and Medicinal Products (BfArM), Bonn  1997 -
Current status of regulation of respiratory sensitizers

Dr. Josje Arts
PSRA manager EMEA
AkzoNobel

Abstract

In this presentation the current status of regulation of respiratory sensitizers will be addressed with a focus on classification criteria and risk assessment.

Emphasis will be on the fact that for respiratory sensitizers - in contrast to skin sensitizers - immunological mechanisms do not have to be demonstrated.
Josje Arts studied human nutrition at the Agricultural University of Wageningen, NL, with toxicology as main subject.

After graduation she started working at TNO (NL) as an inhalation toxicologist for more than 20 years. In that time she was also working on her PhD thesis on animal models for respiratory sensitisation of low molecular weight chemicals (2001).

In 2008 she started working at AkzoNobel, first on REACH registrations, currently she is PSRA Manager EMEA.
Clinical Diagnosis of Occupational Asthma – practice and challenges/opportunities

Dr. Paul Cullinan
National Heart and Lung Institute,
Imperial College

The standard approach to – and some recent advances in - the clinical assessment of occupational asthma will be discussed using a recent ‘case’ managed at the presenter’s hospital; the aim is to provide a clinical perspective to discussions around how the sensitising potential of (chemical) agents encountered at work can be assessed.
Dr. Paul Cullinan
National Heart and Lung Institute,
Imperial College

Paul Cullinan holds a chair in Occupational and Environmental Respiratory Disease at the National Heart and Lung Institute (Imperial College) and is a consultant respiratory physician at Royal Brompton Hospital, London.

He has a long-held interest in the distributions, determinants and prevention of occupational asthma; and leads the UK’s busiest referral centre for the clinical management of the condition (lungsatwork.org.uk).

He is a member of the UK Workplace Expert Health Committee (HSE); and of the UK Industrial Injuries Advisory Council (DWP), for which he is the chair of the research working group.
ABSTRACT

Moving beyond hazard identification towards hazard characterisation:

illustrated with case studies

David Basketter

DABMEB Consultancy Ltd

Sharnbrook, UK

There is a sense in which moving beyond hazard identification in the area of respiratory allergy is rather easy: we do not have any generally applied, let alone validated, predictive tests. Consequently, the presence of hazard is often based on a simple rule, e.g. if the chemical is an isocyanate, we assume it is a respiratory sensitiser, or, if humans will inhale this foreign protein, we should assume that some individuals will raise IgE antibodies. Alternatively, novel respiratory allergens are identified on the basis of the adverse health effects they produce, typically in an occupational setting.

However one arrives at the conclusion that there is a potential hazard present, how can it be characterised? The reality is that very pragmatic approaches have to be adopted. Perhaps a positive result in a skin sensitisation can be subjected to a cytokine profiling study to determine whether there is a Th2 tendency, but that merely leads to a more confident hazard identification. What is missing, for both chemical and protein respiratory allergens is a means to measure their relative sensitising potency. Consequently, a primary strategy has be to consider the exposure side of the “risk = hazard potency x exposure” calculation. Perhaps this is far from what is meant by hazard characterisation in most areas of toxicology, but it is now practical progress is made. The presentation will offer case studies of exposure to a cosmetic containing a potential respiratory sensitiser as well as an occupational example involving exposure to bacterial and fungal protein allergens. In each case, there are clear limitations on what can be achieved.

To progress beyond the pragmatic cases to be discussed, it is obviously necessary to have clarity of focus on mechanism (IgE mediated reactions), one or more methods to assess potency based on the mechanistic understanding and, probably most crucially, to have access to a sufficient body of clinical data which permits a range of respiratory allergens to be ranked according to their relative potency in humans. Whilst that last element remains absent, efforts on methods have very little chance of achieving any degree of scientific or regulatory credibility.
Dr David Basketter

BSc, DSc, FBTS, CBIol, FRSP, FRCPth, FATS

Eurotox Registered Toxicologist

DABMEB Consultancy Ltd

Originally from Manchester, UK, now based in Sharnbrook in North Bedfordshire.

BSc (Hons) in Physiology and DSc in Toxicology from the University of London.

Fellow of the Royal Institute of Biology, the Royal College of Pathology, the British Toxicology Society, the Academy of Toxicological Sciences, USA and the Royal Society of Medicine, London.

1979 - 2007: Worked at the Unilever Safety Laboratory in the UK on allergy and irritation.

2007 - to date: Independent consultant in toxicology, specialising in allergy/irritation.

Honorary member and past President of the European Society of Contact Dermatitis.

Member of the board of examiners of the Royal College of Pathology, London.

Author/co-author of more than 480 papers/chapters on allergy and irritation.

Member of the editorial boards of Dermatitis; Regulatory Toxicology and Pharmacology, the Journal of Immunotoxicology, the Journal of Applied Toxicology, Annali Italiani di Dermatologia Allergologica, Clinica e Sperimentale, and Cutaneous and Ocular Toxicology.

Chair of committees on irritation/allergy topics, including European trade associations for cosmetics and for cleaning products, the European Centre for the Validation of Alternative Methods (ECVAM) Scientific Advisory Committee (ESAC) as well as their skin allergy Validation Management Group and at the Japanese Centre for Validation of Alternative Methods.

Expert adviser to several agencies, including WHO, OECD, EU and other national bodies.

Co-developer of the local lymph node assay (LLNA), the first alternative method to undergo formal regulatory validation. Continuing interests include development of non-animal methods for the identification and assessment of irritants and allergens, development of novel risk assessment methods and establishment of safe exposure limits for skin and respiratory allergens.
ORGANISING COMMITTEE:

Stella Cochrane (Unilver)
Andreas Flueckiger (Hoffmann-La Roche)
Helmut Greim (Technical University, Munich)
Stuart Hindle (Dow)
Ian Kimber (University of Manchester)
Madeleine Laffont (ECETOC)
Alan Poole (ECETOC)
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