

ANNUAL DECLARATION OF INTERESTS (ADoI)

(Please note that high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

Name: EDLER, Lutz

Title: Dr.

Profession: Biostatistician

Current EFSA involvements: Member-CONTAM Panel 2012-2015 (CONTAM), Chair-Aspergillus toxins (CONTAM), Vice-Chair-Chromium and Nickel (CONTAM), Member-Fusarium toxins (CONTAM)

Nature of Activities	Period	Organisation	Subject matter
I. Economic interest			NO INTEREST
II. Member of a management body or equivalent structure	01/2002 - 07/2011	-Name: Central European Society for Anticancer Drug Research (CESAR)-EWIV	Board Member of CESAR-EWIV, CESAR = Central European Society for Anticancer Drug Research SUBJECT: Pharmaceutical drug development through clinical trials in cooperation with pharmaceutical industry. FUNCTION: Responsible Statistician of the Section for Biometry of CESAR-EWIV
	01/2001 - 12/2010	-Name: Central European Society for Anticancer Drug Research (CESAR)-Deutschland	Treasurer of the "Verein" CESAR-Deutschland. CESAR-Deutschland is a "Verein (e.V)" according to German law and as such member of the CESAR-EWIV given the statutes of the CESAR-EWIV.

III. Member of a scientific advisory body	12/2010 - now	-Name: 4SC	<p>Member of the Data Safety Monitoring Board (DSMB) for the clinical Phase I/II Study, called SHORE Study.</p> <p>The remit: Provide advice on the assessment of drug safety and dose escalation of a novel medicinal product for cancer therapy</p> <p>The nature of the advices delivered: Provide advice</p> <p>The experts role: Member</p> <p>Voting in the group, no vetoing</p> <p>Participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	12/2009 - now	-Name: Bundesinstitut für Risikobewertung BfR	<p>Member of the BfR-Kommission on "Kontaminanten und andere gesundheitlich unerwünschte Stoffe in der Lebensmittelkette"</p> <p>The remit: Provide advice on the risk assessment contaminants in food and feed in the food chain</p> <p>The nature of the advices delivered: Provide advice</p> <p>The experts role: Member</p> <p>No voting and no vetoing</p> <p>No direct participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel. The outputs are prepared by the BfR and the committee provides advice for the program and arising issues</p>
	05/2007 - now	-Name: Bundesinstituts für Arzneimittel und Medizinprodukte (BfArM)	<p>Member of Off Label Use in Oncology Expert Group</p> <p>The remit: Provide advice to scientific documents on the off label use of medicinal products for cancer patients provided by invited experts and formulation of a recommendation for the Gemeinsame Bundesausschuss in Germany</p> <p>The nature of the advices delivered: Provide advice</p> <p>The experts role: Member</p> <p>Voting on the recommendation and no vetoing</p> <p>No participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel.</p> <p>or not to the preparation of outputs of the advisory body addressing the same issue as the mandate of the concerned Panel, working group or network.</p>
	03/2007 - now	-Name: Institute of Statistical Mathematics (ISM)	<p>Member of the Scientific Advisory Board (SAB) of ISM</p> <p>The remit: Review of and advice on the research program of the institute</p> <p>The nature of the advices delivered: Provide advice</p> <p>The experts role: Member</p> <p>No voting and no vetoing</p> <p>No participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel.</p>

	06/2006 - now	-Name: University of Heidelberg	<p>Member of the Ethics Committee of the University Clinic</p> <p>The remit: Provide biometrical advice on the scientific and ethical quality of clinical studies The nature of the advices delivered: Review study protocols and patient information and provide advice for changes of the study plan The experts role: Member Voting in the group, no vetoing Participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	01/2006 - now	-Name: University of Heidelberg/National Center for Tumor Disease (NCT)	<p>Member of several Data Safety Monitoring Boards (DSMB) of oncological clinical trials involving novel substances or novel treatment modalities of cancer patients performed by medical clinics of the University Heidelberg and/or the National Center for Tumor Diseases (NCT) Heidelberg.</p> <p>The remit: Provide advice on the assessment of drug safety and efficacy of a novel medicinal product for cancer therapy The nature of the advices delivered: Provide advice The experts role: Member Voting in the group, no vetoing Participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	03/2010 - 07/2012	-Name: EFSA, European Food Safety Authority, Italy, Parma	Member - CONTAM Panel 2009-2012 (CONTAM)
	05/2010 - 04/2012	-Name: EFSA, European Food Safety Authority, Italy, Parma	Member - Statistical Approaches (SC)
	03/2010 - 12/2011	-Name: 4SC	<p>Member of the Data Safety Monitoring Board (DSMB) for the clinical Phase I Study , called AEGIS Study.</p> <p>The remit: Provide advice on the assessment of drug safety and dose escalation of a novel medicinal product for cancer therapy The nature of the advices delivered: Provide advice The experts role: Member Voting in the group, no vetoing Participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	01/2011 - 06/2011	-Name: Medical Research Council UK	<p>Review and evaluation of the Methodology program of the research institute</p> <p>The remit: Review of and advice on the research program The nature of the advices delivered: Provide advice The experts role: Member No voting and no vetoing No participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel.</p>
	04/2009 - 06/2011	-Name: Covance Clinical Research Unit Ltd	<p>Member of the Safety Monitoring Board of POL6326 Clinical Trial in Multiple Myeloma Patients.</p> <p>The remit: Provide advice on the assessment of drug safety and dose escalation of a novel medicinal product for cancer therapy The nature of the advices delivered: Provide advice The experts role: Member Voting in the group, no vetoing Participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>

	12/2010 - 01/2011	-Name: DFG Deutsche Forschungsgemeinschaft	<p>Review of Proposals (1st Round) to the BMBF/ DFG -Programm Clinical Trials to foster clinical trials in Germany with particular assessment of the biostatistical quality of the proposals</p> <p>The remit: Review of and advice on the research proposals The nature of the advices delivered: Provide advice The experts role: Member No voting and no vetoing No participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel.</p>
	05/2010 - 01/2011	-Name: EFSA	<p>Member of the WG on Cadmium Modelling of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance and explanation to the methodology used for the opinion on Cadmium in Food of EFSA issued in 2009 The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>
	02/2010 - 01/2011	-Name: EFSA	<p>Member of the WG on the Benchmark Dose II (BMD II) of the Scientific Committee of EFSA</p> <p>The remit: Provide guidance to use of BMD Software The nature of the advices delivered: Training of EFSA Staff and invited guests on the use of software and summarizing the training material in an opinion The experts role: Member No voting or vetoing in the WG Participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	09/2009 - 07/2010	-Name: EFSA	<p>Member of the WG on Arsenic in Food of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance to risk assessment of arsenic in food The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>
	03/2010 - 06/2010	-Name: EFSA, European Food Safety Authority, Italy, Parma	<p>Member of the WG on Lead in Food of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance to risk assessment of arsenic in food The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>
	03/2010 - 06/2010	-Name: EFSA, European Food Safety Authority, Italy, Parma	<p>Member of the WG on Melamine in Food of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance to risk assessment of arsenic in food The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>

	06/2009 - 03/2010	-Name: EFSA	<p>Member of the WG on Melamine of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance to risk assessment of melamine The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>
	05/2009 - 03/2010	-Name: EFSA	<p>Member of the WG on Lead in Food of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance to risk assessment of lead in food The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>
	12/2009 - 01/2010	-Name: EFSA, European Food Safety Authority, Italy, Parma	<p>Member of the WG on Arsenic in Food of the CONTAM Panel of EFSA</p> <p>The remit: Provide guidance to risk assessment of arsenic in food The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion for the CONTAM Panel</p>
	01/2007 - 12/2009	-Name: ECVAM	<p>Member of the Scientific Steering Committee of the Forum Towards Evidence Based Toxicology EBT</p> <p>The remit: Review of and advice on the conferences program The nature of the advices delivered: Provide advice The experts role: Member No voting and no vetoing No participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel.</p>
	01/2004 - 05/2009	-Name: EFSA	<p>Member of the WG on the Benchmark Dose (BMD) of the Scientific Committee of EFSA</p> <p>The remit: Provide guidance to use the BMD Approach The nature of the advices delivered: Opinion The experts role: Member No voting or vetoing in the WG Participating to prepare the draft opinion to support the mandate of the CONTAM but participating not to the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	05/2006 - 12/2008	-Name: ECVAM	<p>Member of the Expert Group on Reference Standards</p> <p>The remit: Provide advice and prepare a scientific paper The nature of the advices delivered: Publication The experts role: Coauthor No voting or vetoing in the EG No participating at preparation of outputs of the advisory body addressing the same issue as the mandate of the concerned Panel</p>

	01/2005 - 03/2008	-Name: US Environmental Protection Agency (US-EPA), Washington DC, USA	<p>Member of the Federal Insecticide, Fungicide and Rodenticide Act, Scientific Advisory Panel (FIFRA/SAP) providing advice for the risk assessment of carbamates and carbofuranes and for assessing approaches for the development of PBPK models of pyrethroid pesticides.</p> <p>The remit: Provide advice for risk assessment and mathematical modelling The nature of the advices delivered: scientific advice The experts role: Member No voting or vetoing No participating at preparation of outputs addressing the same issue as the mandate of the CONTAM Panel</p>
	01/2007 - 12/2007	-Name: Dept of Education and Research, Federal Gov. Germany	<p>Expert for project evaluation for Novel Therapeutic Approaches</p> <p>The remit: Review of and advice on the research proposals The nature of the advices delivered: Provide advice The experts role: Member No voting and no vetoing No participating at the preparation of outputs addressing the same issue as the mandate of the CONTAM Panel.</p>

IV. Employment	07/1991 - 02/2010	<p>-Name: Deutsches Krebsforschungszentrum (German Cancer Research Center), DKFZ, Heidelberg, Germany, Stiftung des Öffentlichen Rechts der Bundesrepublik Deutschland</p>	<p>The German Cancer Research Center (DKFZ) is a Foundation of Public Law located in Im Neuenheimer Feld 280 69120 Heidelberg Germany. The legal remit is to perform research on cancer and described in full detail in https://www.dkfz.de/de/dkfz/download/Satzung.pdf.</p> <p>The organisation has no official responsibility to carry out risk management and is exclusively engaged in the science risk assessment and evaluation related to the incidence and treatment of cancer.</p> <p>There was no self-employment as consultant related to any business and , in particular , not to food and feed safety.</p> <p>The expert role in the organization and his/her main tasks were during his employment from 1997 to 2010 to perform biostatistical research to support the centers remit by in the design and analysis of experimental and clinical studies of the research on cancer. Since 2006 this role has been extended to the leadership of the Department of Biostatistics comprising the development of scientific concepts on biostatistical research, administration of personnel and development of financial plans for the department and their monitoring and controlling and all other businesses such as reporting the achievements of the department internally and externally, scientific presentations on conferences, review work, grant application and overview of master and PhD theses.</p> <p>As such the Head of the Department of Biostatistics is responsible for theresearch and service program, development of scientific concepts of biostatistics for oncology with special consideration of the needs of the DKFZ, development of the R&D program and outcome reporting, national and interantional representation of the department, participation on programs on continued education, seminars and lecture series, editorial avtivities for scientific journals and advisory activities on biostatistical and methodological issues in national and international boards</p> <p>Retired from the position as department head and from employment on Feb 28, 2010.</p> <p>Research Funding during employment at the DKFZ was exclusively handled by the administration of the DKFZ which distributed the funds ,after taking overhead, to the department and concerned almost exclusively funds for employees who were hired by the DKFZ to work in the department, for biostatistical methods in clinical cancer research. The funds did not exceed the normal budget by more than 25% In the function as department head funds were obtained from the administration of the German Cancer Research Center elicited from private or from the public sector for the research programme of the department under contracts made by the administration of the German Cancer Center with those parties.</p> <p>The private sector includes the pharmaceutical companies Eli Lilly Deutschland, Homburg, Oncoscience Hamburg-Wedel, CESAR-EWIV, Vienna.</p> <p>The public sector includes the University Heidelberg with Heidelberg Clinic and Mannheim Clinic, University of Hamburg, UKE , University of Ulm J and Carreras Foundation, DFG, BMBF, ECVAM,EU</p> <p>No fulltime work for the subject of interest related to EFSA under the full time emploment at the DKFZ.</p>
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V. Ad hoc or occasional consultancy	03/2011 - now	<p>-Name: Deutsches Krebsforschungszentrum (German Cancer Research Center), DKFZ, Heidelberg, Germany, Stiftung des Öffentlichen Rechts der Bundesrepublik Deutschland</p>	<p>The German Cancer Research Center (DKFZ) is a Foundation of Public Law located in Im Neuenheimer Feld 280 69120 Heidelberg Germany. The legal remit is to perform research on cancer and described in full detail in https://www.dkfz.de/de/dkfz/download/Satzung.pdf. The organisation has no official responsibility to carry out risk management and is exclusively engaged in the science risk assessment and evaluation related to the incidence and treatment of cancer.</p> <p>There is no self-employment as consultant related to any business and , in particular , not to food and feed safety.</p> <p>The work reported here concerns Biostatistical research and application of mathematical and statistical methods in the 7th Framework Project BASELINE EU Grant Agreement No 222 738 in a part time contract of 12-34 h/months.</p> <p>The BASELINE project's objective is to provide harmonised and validated sampling strategies, to support the European policies in food safety and to be suitable for food producers, in order to collect comparable data to improve quantitative risk analysis of selected biological and chemical agents.</p> <p>My work for the project is to support workpackage 6 (WP6) on Model Development by supporting the WP 6 leader located at the DKFZ in the development of predictive mathematical models for biological risks and investigate and model sources and pathways of chemical contaminants to improve sampling schemes. This is obtained by a review of existing and definition of new mathematical models in predictive microbiology; investigation of correlations between food risk factors and traceable environmental parameters and contamination indicators; consolidation of existing and new models for microbial growth as a function of intrinsic environmental factors and extrinsic parameters.</p> <p>This employment refers to the previous work for the project done in the function as previous Department Head and previous WP 6 Leader which ended by retirement from the DKFZ in 2010 reported under VI.</p> <p>No fulltime work for the subject of interest related to EFSA under the part time employment at the DKFZ.</p> <p>No provision of advice or services to undertakings, trade associations or other bodies with an interest in the subject matter that falls within EFSA's CONTAM Panel/WG of the CONTAM Panel or related activities.</p>

	09/2009 - 04/2012	-Name: ILSI Europe	<p>Chair of the Expert Group on data selection for Benchmark Dose (BMD) modelling</p> <p>The remit: Chairing and coordinating the sessions to provide guidance to use the BMD Approach</p> <p>The nature of the advices delivered: Publication</p> <p>The experts role: Chair</p> <p>No voting or vetoing in the EG</p> <p>No fulltime consulting.</p>
	07/2009 - 04/2012	-Name: ILSI Europe	<p>Member of Expert Group on data selection for Benchmark Dose (BMD) modelling</p> <p>The remit: Provide guidance to use the BMD Approach</p> <p>The nature of the advices delivered: Publication</p> <p>The experts role: Member</p> <p>No voting or vetoing in the EG</p> <p>No fulltime consulting.</p>
	05/2010 - 12/2010	-Name: Deutsches Krebsforschungszentrum (German Cancer Research Center), DKFZ, Heidelberg, Germany, Stiftung des Öffentlichen Rechts der Bundesrepublik Deutschland	<p>The German Cancer Research Center (DKFZ) is a Foundation of Public Law located in Im Neuenheimer Feld 280 69120 Heidelberg Germany. The legal remit is to perform research on cancer and described in full detail in https://www.dkfz.de/de/dkfz/download/Satzung.pdf.</p> <p>The organisation has no official responsibility to carry out risk management and is exclusively engaged in the science risk assessment and evaluation related to the incidence and treatment of cancer.</p> <p>There was no self-employment as consultant related to any business and , in particular , not to food and feed safety.</p> <p>The work reported here concerns a Partime contract for giving advice to scientists of the Department of Biostatistics in the biostatistical design of animal experiments conducted at the institution.</p> <p>No fulltime work for the subject of interest related to EFSA under the part time emploment at the DKFZ.</p> <p>No provision of advice or services to undertakings, trade associations or other bodies with an interest in the subject matter that falls within EFSA's remit.</p>
	07/2003 - 12/2008	-Name: ILSI Europe	<p>Expert Committee on Eliciting Dose of Allergens in Food</p> <p>The remit: Provide guidance for the risk assessment of allergens</p> <p>The nature of the advices delivered: Publication</p> <p>The experts role: Member</p> <p>No voting or vetoing in EC</p> <p>No fulltime consulting.</p>
VI. Research funding			NO INTEREST
VII. Intellectual property rights			NO INTEREST
VIII. Other membership or affiliation	01/2009 - now	-Name: ISCB	Member of the Executive Board of the International Society of Clinical Biostatistics (ISCB) and Member of the Subcommittees on Congress Organization (Scientific Secretary)and on Regulatory Affairs (SIRA)
	01/2000 - now	-Name: International Statistical Institute ISI	<p>Member of the ISI Committee on Risk Analysis</p> <p>Function::: Member in a scientific society to organize meetings and conferences</p>

	07/2005 - 08/2011	-Name: International Statistical Institute	Chair of the Committee on Risk Analysis (ISI-CRA) Function: Charing a scientific society to organize meetings and conferences
IX. Other relevant interest	05/2011 - now	-Name: Wiley VCH Publisher	Editor of the Biometrical Journal ISSN 0323-3847 joint with a second editor from Italy
	09/2007 - now	-Name: ELSEVIER	Member of the Advisory Board of the Journal"Journal of Computational Statistics and Data Analysis"
X. Interests of close family members			NO INTEREST

I hereby declare that I have read both the Guidance Document on Declarations of Interests and the Procedure for identifying and handling potential conflict of interests and that the above Declaration of Interests is complete.

Date: 09/10/2012 Signature: **SIGNED**