



**Advanced Workshop on:**  
**“Risk assessment of plant protection products, veterinary pharmaceuticals, and animal feed additives: current status and future developments”**

**Chapecó (SC), July 30 – August 3, 2018**



**AIMS:**

The workshop aims to provide participants with an updated status of the Environmental Risk Assessment (ERA) of Plant Protection Products and Veterinary Pharmaceuticals in the European Union, considering the recently published Guidance Documents and the latest developments proposed by the European Food Safety Authority (EFSA) and the European Medical Agency (EMA). The Risk assessment of Animal Feed Additives for target species, consumers, and users will also be addressed according to the most current EFSA outputs.

**LOCATION: SEMINAR - ANFITEATRO AT UNOCHAPECÓ; COURSE – AUDITHORIUM AT BLOCO R. CHAPECÓ – SANTA CATARINA**

For further information, please contact: [workshop\\_ppgca@unochapeco.edu.br](mailto:workshop_ppgca@unochapeco.edu.br). Prof. Dr. Carolina Baretta.

**LECTURERS:**

**PhD. JÖRG RÖMBKE**, ECT Oekotoxikologie GmbH, Flörsheim, Germany

**PhD. FERNANDO RAMOS**, Faculty of Pharmacy, University of Coimbra, Portugal

**PhD. JOSÉ PAULO SOUSA**, Centre for Functional Ecology, Dep. of Life Sciences – University of Coimbra, Portugal

**Dr. DILMAR BARETTA**, Universidade do Estado de Santa Catarina, Centro de Educação Superior do Oeste (UDESC Oeste), Brazil

**Dr. LEONARDO JOSÉ GIL BARCELLOS**, Universidade de Passo Fundo (UPF), Brazil

**Dr. LEANDRO GALON**, Universidade Federal da Fronteira Sul (UFFS), Brazil

**Dr. MARÍLIA HARTMANN**, Universidade Federal da Fronteira Sul (UFFS), Brazil

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<b>SEMINAR (JULY 30 - 31)</b>	
July 30 08 – 09 a.m.	<ul style="list-style-type: none"> <li>• <b>Opening of the workshop – Organizing Committee</b></li> <li>• <b>Introductory notes on the structure of the workshop</b></li> </ul>
July 30 09 – 11:50 a.m.  Coffee break 10:10 – 10:40 a.m.	<ul style="list-style-type: none"> <li>• <b>SEMINAR: Current Status and Challenges of the Environmental Risk Assessment of Plant Protection Products in the European Union</b>, Ph.D. José Paulo Sousa, Department of Life Sciences – University of Coimbra (UC)</li> </ul> <p>The purpose of this seminar is to present an overview of the "modus operandi" of the current ecological risk assessment procedures of pesticides in Europe, so that participants can have a perception of what type of information is required at the European level and how that information is treated to reach the decision to accept or ban an active substance (or commercial formulation). This seminar will also focus on the challenges posed by the new regulation for pesticides in the European Union, especially on the development of Specific Operational Protection Goals (and how the process can be adapted to Brazil), and on the ongoing activities for the development of new guidance documents within the EFSA.</p>
July 30 2 – 4 p.m.  Coffee break 3:20 – 3:50 p.m.	<ul style="list-style-type: none"> <li>• <b>SEMINAR: Veterinary Pharmaceuticals</b>, Ph.D. Jörg Römbke, Co-founder and Managing Director of the private contract research laboratory ECT Oekotoxikologie GmbH (located in Flörsheim/Germany)</li> </ul> <p>The purpose of this seminar is to provide an overview of the current requirements for the environmental impact assessment for Veterinary Medicinal Products (VMP) in Europe, so that participants can have a perception of what type of information is required at the European level. Since such requirements are relatively new, special attention will be given to recent methodological developments. In addition, the very specific conditions of the “ecosystem dung pad” and its high biodiversity will be summarized to understand which protection goals have to be addressed when registering VMPs in Europe. Finally, which measures are necessary when trying to adapt the current EU approach to other regions, such as Brazil, will be presented.</p>
July 30 4:50 – 5:30 p.m.	<ul style="list-style-type: none"> <li>• <b>ROUND TABLE DISCUSSIONS</b>, Dr. Paulo Roger Lopes Alves, Universidade Federal da Fronteira Sul</li> </ul>
July 31 09 – 11:50 a.m.  Coffee break 10:10 – 10:40 a.m.	<ul style="list-style-type: none"> <li>• <b>SEMINAR: Animal Feed Additives</b>, PhD. Fernando Ramos, Faculty of Pharmacy, University of Coimbra, Portugal</li> </ul> <p>This seminar will include an introduction of the EFSA FEEDAP Panel and an in-depth presentation of the EU legal framework on feed additives, including the components of a feed additive dossier and the use of FEEDAP guidance documents to assess risks to target species and consumers. Practical examples on risk assessment and authorization of feed additives will be presented.</p>
July 31 1:40 – 2:50 p.m.	<ul style="list-style-type: none"> <li>• <b>LECTURE 1: Veterinary Pharmaceuticals and Studies with Aquatic Organisms</b>, Dr. Leonardo José Gil Barcelos, Universidade de Passo Fundo.</li> </ul> <p>The purpose of this lecture is to present scientific data on the effects of residues of agrochemicals and drugs from the human occupation of aquatic organisms. The effects of these residues on neuroendocrine and behavioral parameters in non-target organisms will be approached in interspecific relationships with ecological impacts.</p>

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<p>July 31 2:50 – 4:00 p.m.</p>	<ul style="list-style-type: none"> <li>• <b>LECTURE 2: The Current State of Research on Terrestrial Ecotoxicology with Agrochemicals and Veterinary Pharmaceuticals</b>, Dr. Dilmar Baretta, Universidade do Estado de Santa Catarina, Centro de Educação Superior do Oeste (UDESC Oeste). The goal is to present some studies that have been conducted in Brazil, especially those involving agrochemicals and veterinary pharmaceuticals, using soil ecotoxicology as a tool for environmental assessment. Participants will have an idea of major studies conducted in Brazil, especially in the state of Santa Catarina, involving the main products used in agricultural production and, if they can impact the environment, especially the biodiversity of edaphic organisms. And finally, raise research institutions about the importance of these studies and the immediate need to adopt new technologies and develop products that reduce environmental impact, in particular with regards to soil biodiversity.</li> </ul>
<p>4:00 – 4:20 p.m.</p>	<p>Coffee break</p>
<p>July 31 4:20 – 5:30 p.m.</p>	<ul style="list-style-type: none"> <li>• <b>LECTURE 3: Sustainable Management of Agricultural Systems and the Effect of Pesticides on the Environment</b>, Dr. Leandro Galon &amp; Dra. Marília Hartmann, Universidade Federal da Fronteira Sul, Campi Erechim The objective of this seminar is to present an overview of how Brazilian agricultural production is impacting agroecosystems, the main pesticides used for pest control, and technologies that are being used and could not be adopted in Brazil. Thus the participants will have an idea of what can and should be done so that Brazil does not destroy its ecosystems or exert severe impacts on the natural resources in order to produce food. This seminar will also focus on the challenges imposed for Brazilian farmers to start adopting new technologies and using pesticides as the last tool in pest control. In a second moment, the impacts of pesticides on the environment and risk assessment (ERA) of the effects in non-target vertebrates will be approached.</li> </ul>
<p>July 31 5:30 – 6:00 p.m.</p>	<ul style="list-style-type: none"> <li>• <b>ROUND TABLE DISCUSSIONS</b>, Dr. Paulo Roger Lopes Alves, Universidade Federal da Fronteira Sul, Dr. Evandro Spagnollo, Epagri Chapecó.</li> </ul>
<p><b>COURSE (AUGUST 1 – 3)</b></p>	
<p>August 1 Morning</p>	<ul style="list-style-type: none"> <li>• <b>GROUP WORK on Specific Protection Goals for PPP</b>, Ph.D. José Paulo Sousa, Department of Life Sciences – University of Coimbra (UC) Here, the development of Specific Protection Goals (SPGs) will be presented in more detail, and participants will engage in a role-play for the definition of SPGs for different organism groups adapted to Brazil.</li> </ul>
<p>August 1 Afternoon</p>	<ul style="list-style-type: none"> <li>• <b>LECTURE &amp; GROUP WORK: PPP ERA Schemes for In-Soil Organisms and Non-Target Arthropods</b>, Ph.D. José Paulo Sousa, Department of Life Sciences – University of Coimbra (UC) The current RA process for in-soil organisms and NTAs will be presented, together with the new data requirements and the proposed schemes by EFSA. Participants will engage in working examples on ERA for in-soil organisms.</li> </ul>
<p>August 2 Morning</p>	<ul style="list-style-type: none"> <li>• <b>VMP ERA Schemes for Dung Organisms</b>, Ph.D. Jörg Römbke, Co-founder and Managing Director of the private contract research laboratory ECT Oekotoxikologie GmbH (located in Flörsheim/Germany) The current RA process for the dung ecosystem will be presented, together with new data requirements at the higher-tier level (field studies and post-registration)</li> </ul>

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	monitoring). Participants will engage in working examples on ERA for the parasiticide ivermectin.
August 2 Afternoon	<ul style="list-style-type: none"> <li>• <b>VMP RMMs for the Terrestrial Environment</b> , Ph.D. Jörg Römbke, Co-founder and Managing Director of the private contract research laboratory ECT Oekotoxikologie GmbH (located in Flörsheim/Germany)</li> </ul> <p>Many VMPs are not only efficient against parasites but are also toxic for non-target organisms, even at recommended doses. Thus, the environmental risk has to be addressed via specific risk mitigation measures (RMMs). Different options will be presented and whether they are practical under Brazilian conditions will be discussed. Participants will engage in working examples on RMMs for the parasiticide ivermectin.</p>
August 3 Morning	<ul style="list-style-type: none"> <li>• <b>LECTURE: Drug Residue Analysis</b>, PhD Fernando Ramos, Faculty of Pharmacy, University of Coimbra , Portugal</li> </ul> <p>This lecture will be devoted to different theoretical and practical aspects of chemical residue analysis, namely (i) Development of residue testing programs in the EU; (ii) Quality management in the laboratory; (iii) Sampling and sample preparation / management.</p>
August 3 Afternoon	<ul style="list-style-type: none"> <li>• <b>LECTURE: Drug Residue Analysis (cont.)</b>, PhD Fernando Ramos, Faculty of Pharmacy , University of Coimbra , Portugal</li> </ul> <p>Continuing the previous lecture, the addressed topics will be: (i) Screening methods; (ii) Confirmatory methods and result analysis. Participants will engage in group work on examples on residue data.</p>

#### INTERNATIONAL LECTURERS:



**PhD. JÖRG RÖMBKE**, ECT GmbH, Flörsheim, Germany (Email: [j-roembke@ect.de](mailto:j-roembke@ect.de))

Jörg Römbke is the co-founder and Managing Director of the private contract research laboratory ECT Oekotoxikologie GmbH (located in Flörsheim/Germany). He is responsible for ecotoxicological effects and fate tests as well as the environmental risk assessment of chemicals (pesticides, heavy metals, and pharmaceuticals, especially veterinary pharmaceuticals). Dr. Römbke is working both for companies and for national and international governmental authorities. His research includes the effects of various chemical stressors on the environment, in particular soil compartment, both in Central and Southern Europe as well as North Africa and Brazil. He is especially interested in the development and standardization of ecotoxicological test methods both for OECD and ISO (e.g. with dung beetles).



**PhD. FERNANDO RAMOS**, Faculty of Pharmacy, University of Coimbra, Portugal (Email: [framos@ff.uc.pt](mailto:framos@ff.uc.pt))

Fernando Ramos is an Associate Professor at the Faculty of Pharmacy – University of Coimbra. He is developing his research on risk assessment of contaminants and veterinary drug residues in food and feeds. Current research interests include the development and application of analytical methodologies for the study of contaminants and drug residues in food, feeds, and biological fluids in order to obtain a better assessment and risk characterization of the population exposure. Regarding his international experience, he has been a member of the FEEDAP Panel of the European Food Safety Authority since 2013 and a member of the Portuguese Veterinary Medicines Evaluation Group (GAMV) since 2010. He has also been the Vice-chair of the Scientific Committee of the Portuguese Authority for Food Safety (ASAE) since 2008, and a member of the Executive Committee of the AOAC Europe Section since 2006. Since 2003 he has been on the roster of the FAO/WHO JECFA Panel.

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**Ph.D. JOSÉ PAULO SOUSA**, DCV – University of Coimbra, Portugal (E-mail: [ips@zoo.uc.pt](mailto:ips@zoo.uc.pt))

José Paulo Sousa is an Assistant Professor at the Department of Life Sciences – University of Coimbra (UC). He has developed his research on soil ecology and ecotoxicology, especially on risk assessment of pesticides towards soil organisms and on risk assessment for contaminated sites (mainly in Mediterranean countries and Brazil), having published over 140 indexed papers on this topic. Current research interests include: assessing landscape resilience towards habitat change and pesticide use regarding biodiversity and service provision, especially pollination and pest control in Mediterranean systems; and evaluating interactions between climate change and pesticide use on soil communities and service provisioning. Since 2009, he has been a collaborator of EFSA in activities related to ecological risk assessment of pesticides linked to the EFSA PPR Panel. Since 2014, he has been the head of the thematic panel for Pesticides and GMOs for the Portuguese Food Safety Agency (ASAE).

#### **NATIONAL LECTURERS:**



**Dr. DILMAR BARETTA** – Universidade do Estado de Santa Catarina, Centro de Educação Superior do Oeste (UDESC Oeste) (E-mail: [dilmar.baretta@udesc.br](mailto:dilmar.baretta@udesc.br))

He holds a PhD in Soil and Plant Nutrition from USP/ESALQ (2007) with a doctoral stay (2006-2007) at the University of Rouen (France) and at the University of Coimbra (Portugal) under the guidance of Professor José Paulo Sousa (2007). He completed his Postdoctoral studies at USP/ESALQ (2008). Currently, he is an *ad hoc* consultant for more than 10 scientific journals, most of them Qualis A in the area of Agronomy and Animal Science, FAPESP, FAPESC, CAPES, CNPq, and private companies. He has experience in soil science, with emphasis on soil biology: soil fauna and soil biodiversity. He works mainly with soil ecology, soil ecotoxicology, soil quality bioindicators (IBQS, IGQS, QBS), and multivariate analysis. He is an Associate Professor V in the area of Soils and Sustainability of the Department of Animal Science and the Master's Program in Zootecnics & Doctorate in Soil Science of UDESC. He has been an Assistant Editor of RBCS since 2010 and has been a member of the Soil Biology Committee of the Brazilian Society of Soil Science since 2015. He was the Director of Research and Post-Graduation and is currently the General Director of UDESC Oeste (2016-2020). He holds a scholarship for Scientific Productivity from CNPq.



**Dr. LEONARDO JOSÉ GIL BARCELOS** – Universidade de Passo Fundo (UPF) (E-mail: [lbarcellos@upf.br](mailto:lbarcellos@upf.br))

Graduated in Veterinary Medicine (UFRGS), Master's degree in Animal Science (UFRGS), and PhD in Biological Sciences: Physiology (UFRGS). Lecturer at the University of Passo Fundo. He was the coordinator of the Veterinary Medicine Course (2006-2010) and was a member of the University Council (2004-2006 and 2006-2008) and the Board of Directors of Fundação Universidade de Passo Fundo (2007-2010). Vice Rector of Research and Post-Graduation at the University of Passo Fundo (2010-2014, 2014-2018). He conducts research in the areas of stress and behavior of fish and aquatic ecotoxicology. He is a permanent lecturer in the Post-Graduation Programs in Bio-Experimentation and Environmental Sciences at UPF and in Pharmacology at the Federal University of Santa Maria (UFSM). His main organisms under study are jundia fish (*Rhamdia quelen*) and zebrafish (*Danio rerio*) and his main areas of research are physiology of stress response, fish behavior and

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aquatic toxicology. Currently, he advises graduate students at the master's and doctoral levels and supervises postdoctoral fellows. He also works in the area of training in scientific writing, teaching lectures, courses and subjects on the subject in different postgraduate programs at the University of Passo Fundo and other universities. He holds a scholarship for Scientific Productivity from CNPq.



**Dr. LEANDRO GALON** – Universidade Federal da Fronteira Sul (UFFS), Campi Erechim – RS. (E-mail: [leandro.galon@uffs.edu.br](mailto:leandro.galon@uffs.edu.br))

Graduated in Agronomy from the Federal University of Pelotas - UFPel. Master's Degree in Plant Protection – in the knowledge area Weeds - UFPel. PhD in Plant Science (Plant Production), Research line: weeds, allelopathy, herbicides and environmental impact at the Federal University of Viçosa - UFV. He has experience in the field of Agronomy, with emphasis on: biology and weed control, integrated weed management, mathematical modeling for weed damage levels in cultures, agrochemical application technology, tolerance and resistance herbicide selectivity and herbicide efficacy in plants, ecophysiology between cultivated plants and weeds, physiology and herbicide absorption by plants, impact of herbicides on the environment, and influence of herbicides on post crop harvest. Adjunct Professor IV at Universidade Federal da Fronteira Sul, Campus Erechim-RS, Agronomy Course. Creator and leader of the research group Sustainable Management of Agricultural Systems (MASSA), certified by UFFS since 2012. Permanent Professor and Coordinator of the Postgraduate Program in Environmental Science and Technology (PPGCTA) at UFFS. He holds a scholarship for Scientific Productivity from CNPq.



**Dr. MARÍLIA TERESINHA HARTMANN** – Universidade Federal da Fronteira Sul (UFFS), Campi Erechim – RS. (E-mail: [marilia.hartmann@gmail.com](mailto:marilia.hartmann@gmail.com))

Marilia Teresinha Hartmann is an Associate Professor at the Federal University of Fronteira Sul (UFFS), Brazil. She is a supervisor in the master's program in Environmental Science and Technology at UFFS, in the research line Conservation of Natural Resources. She has developed research about the effect of pesticides on non-target organisms, particularly amphibians. Current research interests include: wildlife toxicology, testing the sensitivity of native species to the pesticides present in the natural environment, ecological risk evaluation of pesticides on tadpoles, influence of pesticides on mortality, and behavior and occurrence of teratogenic effects in amphibians, besides micronucleus test to evaluate genotoxicity of pesticides.

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