Klaus Kümmerer

(Editor)

Pharmaceuticals in the Environment
Sources, Fate, Effects and Risks

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Pharmaceuticals in the Environment

Sources, Fate, Effects and Risks

Third edition
With 108 Figures and 62 Tables

Springer

Editor

Prof. Dr. Klaus Kümmerer

Department of Environmental Health Sciences
University Medical Center Freiburg
Breisacher Straße 115 B
79106 Freiburg, Germany
E-mail: klaus.kuemmerer@uniklinik-freiburg.de

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Foreword

When the first green wave appeared in the mid and late 1960s, it was considered a feasible task to solve pollution problems. The visible problems were mostly limited to point sources, and a comprehensive "end of the pipe technology" (= environmental technology) was available. It was even seriously discussed in the US that what was called "zero discharge" could be attained by 1985.

It became clear in the early 1970s that zero discharge would be too expensive, and that we should also rely on the self purification ability of ecosystems. That called for the development of environmental and ecological models to assess the self purification capacity of ecosystems and to set up emission standards, considering the relationship between impacts and effects in the ecosystems. This idea is illustrated in Fig. 0.1. A model is used to relate an emission to its effect on the ecosystem and its components. The relationship is applied to select a good solution to environmental problems by application of environmental technology.

Meanwhile, it has been disclosed that what we could call the environmental crisis is much more complex than we initially thought. We could, for instance, remove heavy metals from wastewater, but where should we dispose the sludge containing the heavy metals? Resource management pointed towards recycling to replace removal. Non-point sources of toxic substances and nutrients, chiefly originating from agriculture, emerged as new threatening environmental problems in the late 1970s. The focus on global environmental problems such as the greenhouse effect and the decomposition of the ozone layer added to the complexity. It was revealed that we use as much as about 100 000 chemicals, which may threaten the environment due to their more or less toxic effects on plants, animals, humans and entire ecosystems. In most industrialised countries comprehensive environmental legislation was introduced to regulate the wide spectrum of different pollution sources. Trillions of dollars have been invested in pollution abatement on a global scale, but it seems that two or more new problems emerge

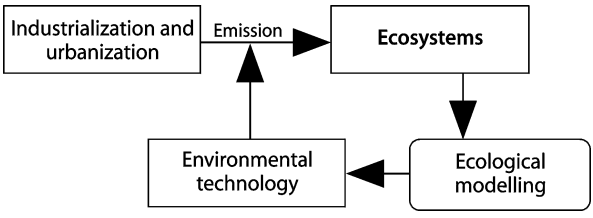

Fig. 0.1. The strategy applied in environmental management in the early 1970s is illustrated. An ecological model is used to relate an emission to its effect on the ecosystem and its components. The relationship is applied to select a good solution to environmental problems by application of environmental technology

for each problem that we solve. Our society does not seem geared toward solving environmental problems, or is there perhaps another explanation?

Recently, standards for environmental management in industries and green accounting have been introduced. The most widely applied standards today for industrial environmental management are the ISO 14000-series. These initiatives attempt to analyse our production systems to find new ways and methods to make our production more environmentally friendly. More than 100 countries have backed up the international standards for effective management of environmental impacts.

Figure 0.2 illustrates how complex environmental management is today. The first figure shows that a simultaneous application of environmental technology, ecotechnology, cleaner technology and environmental legislation is needed in environmental management.

Environmental technology offers a wide spectrum of methods that are able to remove pollutants from water, air and soil. These methods are particularly applicable to coping with point sources.

Cleaner technology explores the possibilities of recycling by-products or the final waste products or attempting to change the entire production technology to obtain reduced emissions. It attempts to answer the pertinent question: couldn't we produce our product using a more environmentally friendly method? It will to a great extent be based on environmental risk assessment, LCA and environmental auditing. The ISO 14000-series and risk reduction techniques are among the most important tools in the application of cleaner technology. The environmental risk assessment of chemicals is in this context a very important tool, as it results in a quantification of the environmental risk.

Ecotechnology covers the use of ecosystems to solve pollution problems, including the erection of artificial ecosystems. It also encompasses the technology that is applicable to the restoration of more or less deteriorated ecosystems. The mentioned classes of technologies cover a wide spectrum of methods. We have, for instance, many environmental technological methods to cope with different wastewater problems, and to

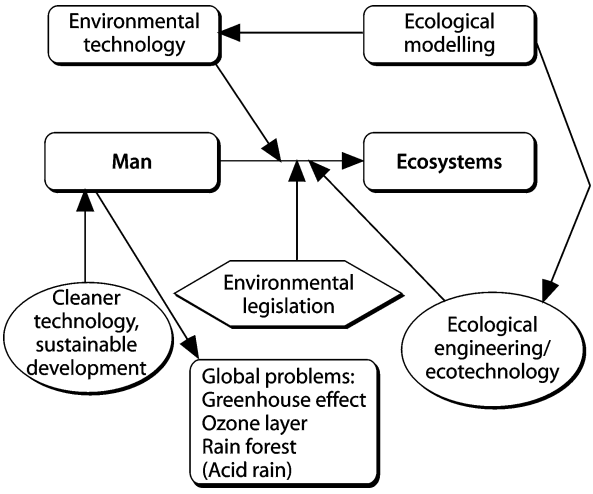

Fig. 0.2. The use of environmental models in environmental management, which, today, is very complex and must apply environmental technology, cleaner technology and ecotechnology. Models are used to select the right environmental management strategy. In addition, the global environmental problems, which also require the use of models as a synthesizing tool, play an increasing role

select the right method or most often the right combination of methods, a profound knowledge of the applicability of the methods and of the processes and characteristics of the ecosystem receiving the emission is necessary.

Environmental legislation and green taxes may be used in addition to these classes of technology. They may in principle be used as regulating instruments in every step of the flow from raw materials and energy to final waste disposal of the used product.

The 20th century has introduced more than 100 000 chemicals that are used in our every day life, either in households, industries or agriculture. We have "blindly" introduced these chemicals without realising the consequences for the environment and directly and indirectly for human health. EU started to list these chemicals in the late 1970s, and since the mid 1980s it has been compulsory to set up an environmental risk assessment for all new chemicals. It was the idea, meanwhile, to make environmental risk assessments for the chemicals already in use, but it is going very slowly, and at the present rate, we shall not be able finish ERAs for all the applied chemicals in this century. Probably, it is necessary to speed up the evaluation of the chemicals in use, for instance by forging a closer cooperation between the environmental agencies and the chemical industry, in order to obtain a realistic picture of the environmental risk associated with the many chemicals we apply today.

It is strange that drugs were not included when a compulsory environmental risk assessment was introduced for new chemicals, because drugs have properties that cause suspicion about environmental effects. Drugs are

- biologically active.
- often mobile as the water solubility is high relative to the molecular weight. This is particularly true for metabolites of the drugs that can be found in urine and therefore also in the wastewater.
- not readily biodegradable.

Drugs have, in other words, properties that make them environmentally interesting.

Today, an environmental risk assessment is required for all new medical compounds used in veterinary drugs, but it is expected that this will also be required for human drugs in the near future.

This volume focuses on what we know but also what we don't know about drugs, or rather what we ought to know to understand the occurrence, the fate and the effect of the about 4 000 medical compounds that we are using in the drugs applied today. What basic knowledge do we have today about drugs to be able to set up ERAs for the medical compounds?

Recently (February 2000) Chemosphere published a special issue on "drugs in the environment." This issue contained several interesting papers on these topics. This volume is, however, the first book to review "drugs in the environment." A book can, of course, give more detailed information than scientific papers, and also make links to what is known more generally about chemical compounds in our environment. The publication of this book is therefore an important step forward in our effort to

1. understand the environmental occurrence and processes of drugs,
2. quantify their effects and risks and

3. properly abate the associated pollution problem by trying to give an answer to the following two pertinent questions:
   - Which medical compounds should be phased out and substituted by other compounds?
   - Could we solve some of the problems with environmental or cleaner technology? How?

At least a decade will pass before we have a proper overview of the many environmental problems that are associated with medical compounds discharged into the environment. At that time – ten or fifteen years from now? – we may have substituted the most environmentally harmful chemicals with other compounds as a concluding result of the performed ERAs. The focal point is, however, that we have a realistic knowledge about the risk involved in the use of medical compounds and can phase out the most risky compounds. This process has already started – slowly but surely – because the medical industry is very concerned today about the fate and effect of antibiotics and recommendations on which antibiotics to use from an environmental point of view can already to a certain extent be given today.

Sven Erik Jørgensen[1]

[1] *Current address*: Prof. Sven Erik Jørgensen, The Royal Danish School of Pharmacy, Department of Analytical and Pharmaceutical Chemistry, Universitetsparken 2, 2100 Copenhagen, Denmark, E-mail: SEJ@dfh.dk.

Preface to the Third Edition

Pharmaceuticals in the environment are still a "hot bed" of interest. Since the publication of the first edition in 2001 and the second edition in 2004 the focus of research has changed again. In the meantime, we have learned quite a lot about the fate, effects, and risks associated with the presence of pharmaceuticals in the aquatic and terrestrial environment. Anyway, there is still an increasing need for knowledge of pharmaceuticals in the environment.

The input and fate of parent compounds and the relative importance of different sources including compounds that up to now have only been scarcely investigated are still of interest. However, metabolites of human and animal metabolism are coming into focus. The same holds for products of transformation of parent compounds and metabolites in the environment, such as dead-end transformation products of biodegradation, oxidation or photolysis.

As it has been extensively demonstrated that the active compounds are present in the environment some of the interest in this field of research has moved from analysis of the compounds, which is still undertaken to effect studies to more extensive fate studies in the lab and in field trials. It has been found that environmental concentrations can cause effects in wildlife if proper tools are applied for effect assessment. The question of mixture toxicity has gained more and more attention. It has been learned that classical tests may underestimate effects and risks. The significance of antibiotic resistance in the environment is still not clear.

The long-awaited guideline for environmental risk assessment for human pharmaceuticals in the European Union has been in force since December 2006. Accordingly, more work has been done in the field of risk assessment and risk management. For compounds already on the market that constitute by far the biggest share this guideline is only applicable in case of the need for a renewal of the license. As for risk management strategies to eliminate pharmaceuticals from waste water or from the effluent of sewage treatment plants have been proposed and investigated. A tremendous amount of literature can now be found describing technical management measures such as oxidative or photolytic effluent treatment, filtering techniques, and application of charcoal. It has been learned however, that each of these approaches has its specific shortcomings. Therefore, additional approaches such as including people handling and using the compounds, and focussing on the properties of the compounds ("green pharmacy") have come into focus.

Accordingly, the 3rd edition has been largely changed again in comparison with the previous ones to address these new issues and the new lines of discussions and new findings. As in the previous editions, it gives an overview of the present state of knowledge presenting typical results and lines of discussion. Like the previous editions, this

one doesn't claim to give a complete overview including the fully detailed body of knowledge of pharmaceuticals in the environment. Rather, it addresses important and typical topics. In contrast, it highlights the most important questions and issues related to the presence of pharmaceuticals in the environment. It also provides many new findings that raise new questions and confirm earlier results.

This edition contains four major parts. In the first part, specifics of pharmaceuticals that distinguish them from "classical" micro-pollutants are addressed. In the second part, new findings on sources, occurrence and fate of pharmaceuticals in the environment are presented. In the third part, an overview of the current state of knowledge of effects of pharmaceuticals in in aquatic and terrestrial environmental is given. New, promising approaches to the study of the effects of pharmaceuticals in the environment are described. The fourth part addresses risk assessment issues starting with the EU guideline and practical experiences of its application. Shortcomings of the EU guidelines are discussed in several contributions. A brief description of the state of regulation of chemicals in Japan is also included. The final part is dedicated to risk management. As advanced STP effluent treatment as a management approach has already been addressed in the second edition and no generally new findings have been published since this time, only little space has been devoted to it. Instead mainly non technical approaches are presented here that are also of importance and are often overseen.

Accordingly, most of the contributions have replaced the ones of the second edition. They are addressing these new foci of research. The remaining ones have been updated. As a result, the 3rd edition is not only a revised and updated one but an additional new volume in a "series" of pharmaceuticals in the environment. The 1st and 2nd edition are still valuable sources of information and should be used together with this 3rd edition. Research needs are addressed within each chapter. Therefore, a separate chapter on research needs was omitted in this edition.

Again the edition of the book would have not been possible without the support of my co-workers in the research group of the Applied Environmental Research Section at the Department of Environmental Health Sciences at the Medical Center at Freiburg University. Special thanks to Radka Alexy, Petra Heiberger and Andreas Längin for their support of my daily routine, which gave me the necessary time to edit a book in such a dynamic field. Numerous discussions with colleagues, with contributors to the book and other people have been stimulating. Thank you to all those people who created the opportunity for discussion, the exchange of ideas and the sharing of results on the role of pharmaceuticals in the environment. This, as well as the encouraging comments and overwhelmingly positive feedback received for the second edition from many experts in the field encouraged the publisher and myself to publish a third edition. Thank you to Christian Witschel and his team from Springer Verlag Heidelberg who strongly supported the idea and helped to make the third edition possible. Thank you also to all the authors who gave up their precious time to contribute to this book.

A big thank you again to my wife Isolde, and my children Sarah and Yannik, with whom I was able to spend precious family time and without whose patience and encouragement neither this nor the preceding editions of the book would ever have been completed.

Klaus Kümmerer
Freiburg, January 2008

Preface to the Second Edition

The first edition of "Pharmaceuticals in the Environment" was sold out within two years. This is quite surprising for a book on such a specialised topic. Obviously, pharmaceuticals in the environment, their fate, effects, and the risks associated with their presence there are a "hot bed" of interest.

Since publication of the first edition, so much literature on the topic has been published in journals and proceedings that it is hard to keep an overview. Most of these papers have been of an analytical nature. The majority deal with the detection of pharmaceuticals in the aquatic environment, while others describe methods used to analyse pharmaceuticals in soil and the results of these analyses. The proportion of publications describing the occurrence and fate of pharmaceuticals in soils has increased since publication of the first edition. A minority of papers describe and assess the effects of pharmaceuticals on organisms in the aquatic environment and in the soil. The initiation of resistance and the selection of resistant bacteria in the environment has been addressed and intensively discussed. However, the significance of this topic is not yet clear. Furthermore, strategies to eliminate pharmaceuticals from waste water or from the effluent of STPs have been proposed and investigated. Introduction of restrictions relating to environmental aspects of pharmaceuticals are being discussed within the scope of EU regulatory procedure.

I have taken the opportunity provided by a second edition to revise and extend the book according to the enlarged body of knowledge on as yet unresolved, as well as newly emerging issues related to the input, occurrence and fate of pharmaceuticals in the environment, as well as the risks which they pose. The new edition gives an overview of the present state of knowledge with respect to typical results and lines of discussion. Like the first edition, this one makes no claim to give a complete overview of the state of the art of pharmaceuticals in the environment. Rather, it addresses important and typical topics and highlights the most important questions and issues related to the presence of pharmaceuticals in the environment. It also provides many new findings which raise new questions and confirm earlier results. The increased number of contributions and authors gathered in the second edition reflects with greater number of papers published, and of issues addressed, as well as the growing number of people from academia, official bodies and companies involved in the topic. It also reflects the intensified and ongoing discussions and the increased public awareness. Thus, in character, the second edition is more that of a general summary than was the case with the first edition.

The second edition of the book would have not been possible without the support of my co-workers in the research group of the Applied Environmental Research Sec-

tion of the Freiburg University Hospital Institute of Environmental Medicine and Hospital Epidemiology. Special thanks to Radka Alexy for her support in my daily routine, which gave me the necessary time to edit a book in such a dynamic field. I greatly acknowledge the support of Franz Daschner, Director of the Institute of Environmental Medicine and Hospital Epidemiolgy. Numerous discussions with colleagues, with contributors to the book and other people have been stimulating. Thank you to all those people who created the opportunity for discussion, the exchange of ideas and the sharing of results on the role of pharmaceuticals in the environment. This, as well as the encouraging comments and positive feedback received to the first edition from many experts in the field encouraged the publisher and myself to publish a second edition so soon after the first edition. Thank you to Christian Witschel and his colleagues from Springer-Verlag Heidelberg, who strongly supported the idea and helped make the second edition possible. Thank you also to all the authors who gave up their precious time to contribute to this book.

A big thank you also to my wife Isolde, and my children Sarah and Yannik, with whom I was able to spend precious family time and without whose patience and encouragement neither this nor the first edition of the book would ever have been completed.

Klaus Kümmerer
Freiburg, November 2003

Preface to the First Edition

All of us use pharmaceuticals for ourselves or for our pets, in husbandry, in agriculture or in aquaculture. But who knows what will happen to the compounds after their administration or use? Are they distributed in the environment or are they eliminated beforehand? What are the possible effects and risks for humans and the environment in connection with the emission of pharmaceuticals into the environment? Pharmaceuticals, diagnostic aids as well as disinfectants used in medicine enter municipal sewage and the aquatic environment. Drugs and growth promoters used in veterinary medicine and husbandry are excreted by animals and emitted into soil via manure or can be part of the runoff from soils after heavy rain fall, which then passes into surface water. Drugs used in aquaculture are passed directly into surface water. Some, such as X-ray contrast media, are excreted completely unchanged, while others are metabolised either into metabolites, which are still active or inactive metabolites. Outdated medications or their remnants are sometimes disposed of down household drains or as (household) waste. The fate, occurrence and effects of pharmaceuticals in the aquatic and terrestrial environment is still mainly unknown.

The disposal of pharmaceuticals in the environment means that a huge number of different substances in different amounts, products and modes of action have to be considered. Therefore, it is difficult to obtain an appropriate overview on the ongoing research. It is even more difficult to identify the most important questions for a systematic approach. The information available is still scarce and not sufficient for sound assessment and decision-making. For this reason, the European Science Foundation (ESF), located in Strasbourg (France), commissioned the workshop "Pharmaceuticals in the Environment." It was held in July 1999 in Freiburg (Germany). The core of the book consists of issues discussed and explored in depth during this workshop. Some other authors, not present at the workshop, have been added.

The book does not claim to give a complete review of the state of the art related to pharmaceuticals in the environment. There is a lot of literature, symposia, international networking and research organising on EDSs. This is still lacking for pharmaceuticals other than hormones. This book gives a short review of the fate, occurence and effects of pharmaceuticals using examples of some typical compounds to highlight the most important questions and issues related to pharmaceuticals in the environment. Input, occurence, fate and effects as well as the possible risks and their assessment are addressed. The book also gives an introduction to this new field of environmental chemistry, ecotoxicology and environmental hygiene.

This book would not have been realised without the workshop "Pharmaceuticals in the Environment" commissioned by the European Science Foundation (ESF). Dr. A. Moth-

Wiklund and her team from the Life and Environment Standing Commitee (LESC) at the ESF always gave good support whenever necessary. All the participants of the workshop contributed to the lively discussions and the identification of the important questions of research in the future. The contributors to this volume were very patient with the editor. The workshop and the book would have not been realised without the support of the director of the Institute of Environmental Medicine and Hospital Epidemiology at the Freiburg University Hospital, Prof. Dr. med. Franz Daschner, and of all my co-workers in the field of pharmaceuticals in the environment. Tina Kümpel and Birgit Stadel helped with the manuscripts. Dr. Witschel from Springer Verlag (Heidelberg) created the opportunity to publish this book. Special thanks to my wife and my children for their encouragement and their support.

Thank you!

Klaus Kümmerer
Freiburg, January 2001

Contents

Contributors

Alder, Alfredo C., Dr.
Swiss Federal Institute of Aquatic Science and Technoloy (Eawag)
Überlandstr. 133
8600 Dübendorf, Switzerland
alder@eawag.ch

Backhaus, Thomas, Dr.
Department of Plant and Environmental Sciences
University of Gothenburg
Carl Skottbergs Gata 22B
40530 Göteborg, Sweden
thomas.backhaus@dpes.gu.se

Benfenati, Emilio, Dr.
Department of Environmental Health Sciences, Mario Negri Institute for Pharmacological Research
Via Eritrea 62
20157 Milan, Italy
benfenati@marionegri.it

Blanck, Hans, Prof.
Dep. of Plant and Env. Sciences
Göteborg University
Carls Skottsbergs Gata 22 b
Box 461
40530 Göteborg, Sweden

Boxall, Alistair B.A., Prof.
Central Sciences Laboratory
Sand Hutton
York Y041 1LZ, United Kingdom
a.boxall@csl.gov.uk

Bugnon, Olivier, Adjunct Prof.
Community Pharmacy Research Unit
Section of Pharmaceutical Sciences
University of Geneva and University of Lausanne
Pharmacie PMU, Rue du Bognon 44
1011 Lausanne, Switzerland
olivier.bugnon@hospvd.ch

Calamari, Davide, Prof. Dr.
University of Insubria, Department of Structural and Functional Biology
Environmental Research Group
Via J. H. Dunant 3
21100 Varese VA, Italy
davide.calamari@uninsurbia.it

Castensson, Staffan, Ph.D., Assoc. Prof.
R&D Department
Apoteket AB
118 81 Stockholm,Sweden
staffan.castensson@apoteket.se

Cleuvers, Michael, Dr.
Head of Business Unit Industrial Chemicals – REACh
Dr. Knoell Consult GmbH
Marie-Curie-Straße 8
51377 Leverkusen, Germany
mcleuvers@dr-knoell-consult.com

Cunningham, Virginia L., Dr.
ClaxoSmithKline
200 North 16th St.
Philadelphia, PA 19102, USA
Cunningham_v@msn.com

Di Guardo, Antonio, Dr.
University of Insubria
Department of Structural and Functional Biology
Via J. H. Dunant 3
21100 Varese VA, Italy
antonio.diguardo@uninsurbia.it

Fanelli, Roberto, Dr.
Department of Environmental Health Sciences
Mario Negri Institute for Pharmacological Research
Via Eritrea 62
20157 Milan, Italy
fanelli@marionegri.it

Feldmann, Dirk F., Dr.
Bausch & Lomb/Dr. Mann Pharma
Brunsbüttler Damm 165-173
13581 Berlin, Germany
dirk.feldmann@bausch.com

Fenner, Kathrin, Dr.
Swiss Federal Institute of Aquatic Science and Technoloy (Eawag)
Überlandstr. 133
8600 Dübendorf, Switzerland
kathrin.fenner@eawag.ch

Fent, Karl, Prof. Dr.
University of Applied Sciences Northwestern Switzerland
School of Life Sciences and Swiss Federal Institute of Technology Zürich (ETHZ)
Gruendenstraße 40
4132 Muttens, Switzerland
karl.fent@bluewin.ch

Fick, Jerker
Umeå University
Environmental Chemistry
901 87 Umeå, Sweden
jerker.fick@chem.umu.se

Gunnarsson, Bo, Dr.
Apoteket AB
Söndermalmsallén 36
118 81 Stockholm, Sweden
bo.gunnarsson@apoteket.se

Halling-Sørenson, Bent, Prof.
Faculty of Pharmaceutical Sciences
Copenhagen University
Universitetsparken 2
2100 Copenhagen, Denmark
bhs@farma.ku.dk

Hamscher, Gerd, Prof. Dr.
University of Veterinary Medicine, Foundation
Institute for Food Toxicology
Bischofsholer Damm 15
30173 Hannover, Germany
gerd.hamscher@tiho-hannover.de

Hartung, Jörg, Prof. Dr.
University of Veterinary Medicine, Foundation
Insitute for Animal Hygiene, Animal Welfare and Behaviour of Farm Animals
Bünteweg 17p
30559 Hannover, Germany
itt@tiho-hannover.de

Heberer, Thomas, PD Dr.
Director of the Food Institute Oldenburg (LI-OL)
Lower Saxony Federal State Office of Consumer Protection and Food Safety (LAVES)
Martin-Niemöller-Straße 2
26133 Oldenburg, Germany
Thomas.Heberer@laves.niedersachsen.de

Henriques, Danielle Marranquiel, M.Sc.
Universidade Federal de Santa Maria
Departamento de Quimica da UFSM,
Prédio 18 Campus Camobi
97105-900 Santa Maria, RS, Brasil
danielle@mail.ufsm.br

Hickmann, Silke
Umweltbundesamt
Wörlitzer Platz 1
06844 Dessau-Roßlau, Germany
silke.hickmann@uba.de

Hutchinson, Thom, Prof.
Associate Director Environmental Safety Assessment
AstraZeneca Global Safety, Health & Environment
Brixham Environmental Laboratory
Brixham, Devon TQ5 8BA
United Kingdom
tom.hutchinson@astrazeneca.com

Kallenborn, Roland, Prof. Dr.
University Centre in Svalbard (UNIS)
Street 230 house 1, P.O. Box 156
9171 Longyearbyen, Norway
roland.kallenborn@unis.no

Klaschka, Ursula, Prof. Dr.
University of Applied Sciences Ulm
Prittwitzstr. 10
89075 Ulm, Germany
Klaschka@hs-ulm.de

Knacker, Thomas, Dr.
ECT Oekotoxikologie GmbH
Böttgerstraße 2-14
65439 Flörsheim a. M., Germany
th-knacker@ect.de

Koschorreck, Jan
Umweltbundesamt
Corrensplatz 1
14195 Berlin, Germany
jan.koschorreck@uba.de

Krogh, Kristine, Prof.
Faculty of Pharmaceutical Sciences
Copenhagen University
Universitetsparken 2
2100 Copenhagen, Denmark
kak@farma.ku.dk

Lapen, David R., Dr.
Agriculure and Agri-Food Canada
Central Experimental Farm
Ottawa, Ontario K1A 0C6, Canada
lapend@agr.gc.ca

Larsbo, Mats, Dr.
Department of Soil Sciences,
Swedish University of Agricultural Scienes
Box 7014
750 07 Uppsala, Sweden
mats.larsbo@mv.slu.se

Larsson, D. G. Joakim, PhD, Assoc. Prof.
Institute of Neurosciences and Physiology,
the Sahlgrenska Academy at the University of Gothenburg
Box 434
405 30, Gothenburg, Sweden
joakim.larsson@fysiologi.gu.se

Ledin, Anna Birgitta, Prof. PhD
Technical University of Denmark
Department of Environmental Engineering
Street Bygningstorvet, Building 115
2800 City Kgs. Lyngby, Denmark
anl@env.dtu.dk

Liebig, Markus, Dr.
ECT Oekotoxikologie GmbH
Böttgerstraße 2-14
65439 Flörsheim a. M., Germany
m-liebig@ect.de

Lindberg, Richard
Umeå University
Environmental Chemistry
901 87 Umeå, Sweden
richard.lindberg@chem.umu.se

Martins, Ayrton Figueiredo, Prof. Dr.
Universidade Federal de Santa Maria
Departamento de Quimica da UFSM,
Prédio 18, Campus Camobi
97105-900 Santa Maria, RS, Brasil
martins@quimica.ufsm.br

Metcalfe, Chris, Prof.
Environmental and Resource Studies
Trent University
1600 West Bank Drive
Peterborough, Ontario, K9J 7B8, Canada
cmetcalfe@trentu.ca

Moe, Morten K.
Norwegian Institute for Air Research (NILU)
Polar Environmental Centre
9296 Tromsø, Norway
mkm@nilu.no

Moltmann, Johann F., Dr.
ECT Oekotoxikologie GmbH
Böttgerstraße 2-14
65439 Flörsheim a. M., Germany
j-moltmann@ect.de

Montforts, Mark, Dr.
National Institute for Public Health and the Environment
Expertise Centre for Substances
P.O. Box 1
3720 BA Bilthoven, The Netherlands
mark.montforts@rivm.nl

Nentwig, Gerrit, Dr.
Insitute for Ecology, Evolution and Diversity
Department Aquatic Ecotoxicology
Siesmayerstraße 70
60054 Frankfurt, Germany
nentwig@em.uni-frankfurt.de

Nielsen, Kåre M.
Tromsø University
Department of Pharmacy
9037 Tromsø, Norway
kaare.nielsen@farmasi.uit.no

Niquille, Anne, Pharmacist PhD Candidate
Community Pharmacy Research Unit, Section of Pharmaceutical Sciences
University of Geneva and University of Lausanne
Pharmacie PMU, Rue du Bugnon 44
1011 Lausanne, Switzerland
anne.niquille@hospvd.ch

Patureau, Dominique, Dr.
Chargée de Recherche INRA
INRA, URO50, Laboratoire de Biotechnologie de l'Environnement
Avenue des Etangs
11100 Narbonne, France
patureau@supagro.inra.fr

Römbke, Jörg, Dr.
ECT Oekotoxikologie GmbH
Böttgerstraße 2-14
65439 Flörsheim a. M., Germany
j-roembke@ect.de

Schmitt, Heike, PhD
IRAS, Utrecht University
Yalelaan 2
3584 CM Utrecht, The Netherlands
h.schmitt@uu.nl

Silveira Frank, Carla da, M.Sc.
Universidade Federal de Santa Maria
Departamento de Quimica da UFSM, Prédio 18 Campus Camobi
97105-900 Santa Maria, RS, Brasil
dasilveirafrank@gmail.com

Straub, Jürgen Oliver, Dr. EuroProBiol. CBiol. MIBiol.
F. Hoffmann-La Roche Ltd.
Corporate Safety, Health & Environmental Protection
CSE, 49/2.033
4070 Basel, Switzerland
juerg.straub@roche.com

Sumpter, John, Prof.
Inst. for the Environment
Brunel University
Uxbridge,
Middlesex UB8 3PH, United Kingdom

Ternes, Thomas A., Dr.
Bundesanstalt für Gewässerkunde (BfG)
Am Mainzer Tor 1
56068 Koblenz, Germany
ternes@bafg.de

Topp, Edward, Dr.
Agriculture and Agri-Food Canada
1391 Sandford Street
London, Ontario N5V 4T3, Canada
toppe@agr.gc.ca

Tysklind, Mats
Umeå University
Environmental Chemistry
901 87 Umeå, Sweden
Mats.Tysklind@chem.umu.se

Vasconcelos, Tibiriçá Gonçalves, Dr.
Universidade Federal de Santa Maria
LAMIC, Predio 44, 3 andar, Campus Camobi
97105-900 Santa Maria, RS, Brasil
tgvasconcelos@yahoo.com.br

Vasskog, Terje
Tromsø University
Department of Pharmacy
9037 Tromsø, Norway
terje.vasskog@farmasi.uit.no

Wennmalm, Åke, Prof.
Chief Executive Board
P.O. Box 22550
104 22 Stockholm, Sweden
ake.wennmalm@sll.se

Yoshioka, Yoshitada, Prof. Dr.
Faculty of Education and Welfare
Oity University
700 Dannoharu
870-1192 Oita, Japan
yoshioka@cc.oita-u.ac.jp

Zuccato, Ettore, Dr.
Department of Environmental Health
Sciences, Mario Negri Institute for
Pharmacological Research
Via Eritrea 62
20157 Milan, Italy
zuccato@marionegri.it