Dear Prof. Glover,

We, the undersigned are writing to draw your attention to imminent decisions by the European Commission to set a regulatory framework for so-called endocrine disrupting chemicals. We are concerned that the approach proposed could rewrite well-accepted scientific and regulatory principles in the areas of toxicology and ecotoxicology without adequate scientific evidence justifying such a departure from existing practices.

First of all, we want to emphasize that “endocrine disruption” is not a toxicological endpoint, but one of many mechanisms which may cause adverse effects. In addition, we recognise that such a policy initiative is highly technical and complex and requires an understanding of the modes of action for endocrine disruption and their significance. It also implies the in-depth involvement not only of toxicological disciplines but also of environmental sciences and thus requires scientific input from experts in this area. The undersigned are concerned that the Commission’s scientific committees have so far not been consulted by the Commission when drafting such regulations. What is even more disturbing is that, where a scientific advisory body such as EFSA has been consulted, critical elements of this body’s opinion are ignored. For example, in assessment of chemicals with endocrine activity, EFSA supported a substance specific risk assessment approach integrating exposure and adverse effects instead of developing horizontal criteria for defining whether a substance is an “endocrine disruptor”. Development of horizontal lists ignores the long-standing principle that an assessment of a substance should be based on data obtained from toxicity testing on this specific substance and derived information on potency.

If the Commission will adopt a policy stating that it is impossible to define a safe limit or threshold for a substance with classified as endocrine disruptor, this would reverse current scientific and regulatory practices and, more importantly, ignore broadly developed and accepted scientific development and accepted knowledge regarding thresholds of adversity. Moreover, the latter approach may not only apply to potential EDCs but rather would apply to all chemical substances and thus nullify decades of experience and repeatable observations in exposure-response relationships in pharmacology and toxicology and well-established and widely proven procedures in hazard and risk assessment.
It also appears that the Commission will propose that identification of an in vitro effect without a causal relationship to adversity in an intact organism may be sufficient to classify a substance as an “endocrine disruptor”. This would not only represent a rewriting of the rules and accepted practices of toxicology, which rely on well-defined adverse effects observed in adequately performed studies, but also would be contrary to all accumulated physiological understanding.

This leaves us concerned that there is neither a scientific basis nor broad support by scientists established in risk assessment behind the approach of setting horizontal criteria and the lists of confirmed and suspected “endocrine disruptors”.

We have noted your important interventions on the need for scientific evidence to be at the heart of EU policy and are therefore writing to urge your review of the emerging policy to ensure that the opinion of relevant scientific committees and member states authorities are taken into account.

The following individuals are supporting this initiative:

Antero Aitio, Dr. Med. Sc., Professor h.c., former scientist/medical officer at the International Programme on Chemical Safety, World Health Organization; former team leader, Finnish Institute of Occupational Health; former Unit Chief of the Monographs Programme, International Agency for Research on Cancer

Herman Autrup, Professor, PhD ATS, President International Union of Toxicologists, former member SCHER, AFC-Panel of EFSA, Institute of Public Health, University of Aarhus, Denmark

Susan, Barlow, Ph.D., former member of EFSA Scientific Committee (2003---2012), Brighton, UK

Diane Benford, Dr., member, chair CONTAM Panel of EFSA, Head of Chemical Risk Assessment Unit, Food Standards Agency, London, UK

Ole J. Bjerrum, DMSc, Professor of Pharmacology, University of Copenhagen, Denmark

Sir Colin Berry, Prof. Emeritus of Pathology, Queen Mary, University of London, UK

Bas J. Blaauuboer, Prof. Dr., Doerenkamp-Zbinden Chair on Alternatives to Toxicity Testing, Institute for Risk Assessment Sciences, Division of Toxicology, Utrecht University, The Netherlands

Hermann M. Bolt, Prof. Dr. med., Dr. rer. nat., Chair of the Scientific Committee for Occupational Exposure Limits, SCOEL (DG Employment), Leibniz Research Centre for Working Environment and Human Factors (IfADo) at the TU Dortmund, Germany

Alan Boobis, Prof., OBE, PhD, FSB, FBTS, member CONTAM Panel of EFSA, Centre for Pharmacology & Therapeutics, Department of Medicine, Imperial College London, UK
Christopher J. Borgert, Ph.D., President & Principal Scientist, Applied Pharmacology and Toxicology, Inc., Research Assistant Scientist, Department of Physiological Sciences, College of Veterinary Medicine, Gainesville, FL, USA

Alexander Bürkle, Prof. Dr., Chair of Molecular Toxicology Department of Biology, University of Konstanz, Germany

Michèle Bouchard, Ph.D., Associate Professor, Head of the Chair in Toxicological Risk Assessment and Management and Head of the Biomarker Unit of the Xenobiotics and Nanoparticles Platform, Department of Environmental and Occupational Health, Faculty of Medicine, University of Montreal, Canada

Thomas Colnot, Ph.D., ERT, CiS Toxicology, Castro, Chile

Brian Cummings, Ph.D., Assistant Professor, Department of Pharmaceutical and Biomedical Sciences, University of Georgia, Athens, GA, USA

Slawomir Czerczak, Prof. Dr., Chair for Group of Experts for Chemical Agents of Polish Intersectoral Commission for MAC and MAI Values, Head of Department of Chemical Safety, Nofer Institute of Occupational Medicine Lodz, Poland

Gisela H. Degen, Prof. Dr., member SCCS, Leibniz Research Centre for Working Environment and Human Factors (IfADo) at the TU Dortmund, Germany

Wolfgang Dekant, PhD, Professor of Toxicology, former member SCHER, CSTEE, member SCENIHR, Department of Toxicology, University of Würzburg, Germany

Lennart Dencker, Prof. Dr., Department of Pharmaceutical Biosciences, Uppsala University, Uppsala, Sweden

Daniel Dietrich, Prof. Dr., Ph.D., Professor of Human and Environmental Toxicology, Member of SCENIHR, Former Chair of the OECD Endocrine Disruption and Ecotoxicology EDTA-VMG Non-Animal of the OECD, Member Presidential Expert Group AOAC, Faculty of Biology, University of Konstanz, Germany

Daniel R. Doerge, Ph.D., National Center for Toxicological Research, Jefferson, AR, USA (affiliation is given for identification purposes only)

Eugenia Dogliotti, Dr., Member CONTAM Panel of EFSA, Istituto Superiore di Sanità, Environment & Primary Prevention Dept., Unit of Molecular Epidemiology, Roma, Italy

Jose L. Domingo, Professor and Director, Laboratory of Toxicology and Environmental Health, School of Medicine, Universitat "Rovira i Virgili", Reus, Spain

Johanna Fink-Gremmels, Prof. Dr., Utrecht University, Faculty of Veterinary Medicine, Institute for Risk Assessment Sciences, Division Toxicology, Veterinary Pharmacology, Pharmacotherapy and Toxicology, Utrecht, The Netherlands

Hermann Fromme, Prof. Dr., Department of Chemical Safety and Toxicology, Bavarian Health and Food Safety Authority, Munich

Corrado Galli, Pof. Dr., Dean, Faculty of Pharmaceutical Sciences, Lab. Toxicology, Department of Pharmacological and Biomolecular Sciences, University of Milan, Italy
Hannu Komulainen, Research professor, former member SCHER, National Institute for Health and Welfare, Department of Environmental Health, Kuopio, Finland

Hans Lepper, Dr., Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, SG K3: Forschungskoordination/Zentralstelle Risikoanalyse, Erlangen, Germany

Beatriz Silva Lima, Prof. Dr., Lisbon University, Faculty of Pharmacy, Lisbon, Portugal

Jan Linders, Dr., member SCHER, formerly National Institute for Public Health and the Environment (RIVM), The Netherlands

Marcello Lotti, MD, Professor, University of Padua, Medical School, Padua, Italy

Marina Marinovich, Prof. Dr., Faculty of Pharmaceutical Sciences, Lab. Toxicology, Department of Pharmacological and Biomolecular Sciences, University of Milan, Italy

Angelo Moretto, Prof. Dr., Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Milano, Italy

Paquale Mosesso, Associate Professor of Genetics, member ANS Panel of EFSA, Department of Ecological and Biological Sciences, University of Tuscia, Viterbo, Italy

Mikko Nikinmaa, Prof. Dr., Department of Biology, University of Turku, Finland

Marc Pallardy, Prof. Dr., INSERM UMR 996, University Paris-Sud, Faculty of Pharmacy, Chatenay-Malabry, France

Markku Pasanen, Prof. Dr., University of Eastern Finland, Faculty of Health Sciences, School of Pharmacy, Kuopio, Finland

Olavi Pelkonen, Professor of Pharmacology, Department of Pharmacology and Toxicology, University of Oulu, Oulu, Finland

Hannu Raunio, Prof. Dr., University of Eastern Finland, Faculty of Health Sciences, School of Pharmacy, Kuopio, Finland

Ivonne M.C.M. Rietjens, Prof. dr. ir., Professor in Toxicology, member ANS Panel of EFSA, Wageningen University AFSG/ Division of Toxicology, Wageningen, The Netherlands

Konrad Rydzynski, Prof. Dr. med., Coordinator of the European Network of Excellence ECNIS (Environmental Cancer Risks, Nutrition and the Individual Susceptibility), member SCENIHR, Director of the Nofer Institute of Occupational Medicine, Lodz, Poland

Edward V. Sargent, Dr., MPH, PhD DABT, Adjunct Full Professor, School of Public Health, Rutgers University, NJ, USA

Tinaa Santonen, MD, PhD, MSc in Applied Toxicology Team Leader, Chemical Safety, Finnish Institute of Occupational Health, Finland

Josef Schlatter, Dr., member of EFSA Scientific Committee, Zürich, Switzerland
Dieter Schrenk, MD PhD, Professor of Toxicology, member CONTAM Panel of EFSA, Food Chemistry and Toxicology University of Kaiserslautern, Germany

Richard M Sharpe, Prof. Dr., MRC Centre for Reproductive Health, The Queen's Medical Research Institute, University of Edinburgh, Scotland, UK

Andrzej C Skladanowski, PhD, Prof. Dr., Medical University of Gdansk Intercollegiate Faculty of Biotechnology UG-MUG, Department of Molecular Enzymology, Gdansk, Poland

Ralf Stahlmann, Prof. Dr. med., Institut für Klinische Pharmakologie und Toxikologie, Charité Universitätsmedizin Berlin, Germany

Frank M. Sullivan, BsC (Hons), FBTS, formerly UK Specialist in Reproductive Toxicology

James A. Swenberg, DVM, PhD, DACVP, Kenan Distinguished Professor of Environmental Sciences and Engineering, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, NC USA

Emanuela Testai, Dr., former member SCHER, CSTEE, member SCENIHR, Istituto Superiore di Sanità, Environment & Primary Prevention Dept., Mechanisms of Toxicity Unit, Roma, Italy

Jouko Tuomisto, MD, PhD, Professor emeritus, Department of Environmental Health, THL (National Institute for Health and Welfare), Kuopio, Finland

N.P.E. Vermeulen, Prof. Dr., AIMMS / LACDR-Section of Molecular Toxicology, Dept. of Chemistry & Pharmaceutical Sciences, VU University, Amsterdam, The Netherlands

Marco Vighi, Prof. Dr., former member SCHER, Department of Earth and Environmental Sciences, University of Milano Bicocca, Milano, Italy

Matti Viluksela, Prof. Dr., former member SCHER, National Institute for Health and Welfare Department of Environmental Health, Kuopio, Finland and University of Eastern Finland Department of Environmental Science Kuopio, Finland

Wolfgang Völkel, PD Dr., ERT, Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Sachgebiet Chemikaliensicherheit und Toxikologie/Bionitoring, München, Germany

J.C. Vos, Dr., Dept. of Chemistry & Pharmacochemistry, AIMMS-Section of Molecular Toxicology, Vrije Universiteit, Amsterdam, The Netherlands

Wojciech Wasowicz, Prof. Dr., President of the Polish Society of Toxicology, Nofer Institute of Occupational Medicine, Lodz, Poland