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A European perspective on alternatives to animal testing for environmental hazard identification and risk assessment



Stefan Scholz^{a,*}, Erika Sela^b, Ludek Blaha^{c,1}, Thomas Braunbeck^{d,2}, Malyka Galay-Burgos^{e,3}, Mauricio García-Franco^{b,4}, Joaquin Guinea^b, Nils Klüver^{a,5}, Kristin Schirmer^{f,g,h,6}, Katrin Tanneberger^{f,6}, Marysia Tobor-Kapłonⁱ, Hilda Witters^{j,7}, Scott Belanger^{k,8}, Emilio Benfenati^{l,9}, Stuart Creton^{m,10}, Mark T.D. Cronin^{n,11}, Rik I.L. Eggen^{o,h,12}, Michelle Embry^{p,13}, Drew Ekman^q, Anne Gourmelon^r, Marlies Halder^{s,14}, Barry Hardy^t, Thomas Hartung^{u,15}, Bruno Hubesch^{v,16}, Dirk Jungmann^{w,17}, Mark A. Lampi^{x,18}, Lucy Lee^{y,19}, Marc Léonard^{z,20}, Eberhard Küster^{a,5}, Adam Lillicrap^{aa,21}, Till Luckenbach^{a,5}, Albertinka J. Murk^{ab}, José M. Navas^{ac,22}, Willie Peijnenburg^{ad,ae,23}, Guillermo Repetto^{af,24}, Edward Salinas^{ag,25}, Gerrit Schüürmann^{ah,ai,26}, Horst Spielmann^{aj}, Knut Erik Tollefsen^{aa,21}, Susanne Walter-Rohde^{ak,27}, Graham Whale^{al,28}, James R. Wheeler^{am}, Matthew J. Winter^{an,29}

* Corresponding author. Fax: +49 341 235 1787.

E-mail addresses: stefan.scholz@ufz.de (S. Scholz), esela@zfbiolabs.com (E. Sela), blaha@recetox.muni.cz (L. Blaha), braunbeck@uni-hd.de (T. Braunbeck), malyka.galay-burgos@ecetoc.org (M. Galay-Burgos), mgarcia@zfbiolabs.com, mauricio.garciafranco@gmail.com, mauricio.gf@aquacria.com (M. García-Franco), jguinea@zfbiolabs.com (J. Guinea), nils.kluever@ufz.de (N. Klüver), kristin.schirmer@eawag.ch (K. Schirmer), marysia.tobor-kaplon@wilresearch.com (M. Tobor-Kapłon), hilda.witters@vito.be (H. Witters), belanger.se@pg.com (S. Belanger), benfenati@marionegri.it (E. Benfenati), stuart.creton@nc3rs.org.uk, stuart.creton@epa.govt.nz (S. Creton), m.t.cronin@ljamu.ac.uk (M.T.D. Cronin), rik.eggen@eawag.ch (R.I.L. Eggen), membry@ils.org (M. Embry), ekman.drew@epa.gov (D. Ekman), anne.gourmelon@oecd.org (A. Gourmelon), marlies.halder@ec.europa.eu (M. Halder), barry.hardy@douglasconnect.com (B. Hardy), thartung@jhsph.edu (T. Hartung), bhu@cefic.be (B. Hubesch), dirk.jungmann@tu-dresden.de (D. Jungmann), mark.a.lampi@exxonmobil.com (M.A. Lampi), lucy.lee@ufv.ca (L. Lee), mleonard@rd.loreale.com (M. Léonard), eberhard.kuester@ufz.de (E. Küster), adam.lillicrap@niva.no (A. Lillicrap), till.luckenbach@ufz.de (T. Luckenbach), tinka.murk@wur.nl (A.J. Murk), jmnavas@inia.es (J.M. Navas), willie.peijnenburg@rivm.nl (W. Peijnenburg), grepkuh@upo.es (G. Repetto), edward.salinas@basf.com (E. Salinas), gerrit.schuermann@ufz.de (G. Schüürmann), horst.spielmann@fu-berlin.de (H. Spielmann), knut.erik.tollefsen@niva.no (K.E. Tollefsen), susanne.walter-rohde@uba.de (S. Walter-Rohde), graham.whale@shell.com (G. Whale), james.wheeler@syngenta.com (J.R. Wheeler), matthew.winter@astrazeneca.com (M.J. Winter).

¹ Fax: +420 54949 2840.

² Fax: +49 (0)6221 546162.

³ Fax: +32 2 675 3625.

⁴ Present address: AQUACRIA C.A.C./Albeniz, 20 (Urb. El Mirador)Valdetorres del Jarama. 24150 (Madrid) Spain. Tel.: +34-617740501.

⁵ Fax: +49 341 235 1787.

⁶ Fax: +41 44 823 53 11.

⁷ Fax: +32 14 582657.

⁸ Fax: +1 513 277 8356.

⁹ Fax: +39 02 39014735.

¹⁰ Current address: Environmental Protection Authority, 215 Lambton Quay, Wellington 6140, New Zealand.

¹¹ Fax: +44 151 231 2170.

¹² Fax: +41 (0)58 765 5898.

¹³ Fax: +1 202 659 3617.

¹⁴ Fax: +39 0332 786297.

¹⁵ Fax: +1 410 614 2871.

¹⁶ Fax: +32 2 676 7392.

¹⁷ Fax: +49 351 463 37108.

¹⁸ Fax: +32 (0)2 722 4228.

¹⁹ Fax: +1 604 859 6653.

²⁰ Fax: +33 1 48 68 89 27.

²¹ Fax: +47 22185200.

²² Fax: +34 913572293.

²³ Fax: +31 30 2744413.

²⁴ Fax: +34 954349813.

²⁵ Fax: +49 621 60 58043.

²⁶ Fax: +49 341 235 1785.

²⁷ Fax: +49 340 2104 2330.

²⁸ Fax: +44 0151 373 5406.

²⁹ Fax: +44 1803 882974.

- ^aUFZ – Helmholtz Centre for Environmental Research, Department of Bioanalytical Ecotoxicology, 04318 Leipzig, Germany
- ^bZF Biolabs, Ronda de Valdecarrizo 41B, Bajo, 28760 Tres Cantos (Madrid), Spain
- ^cMasaryk University, Faculty of Science RECETOX (Research Centre for Toxic Compounds in the Environment), Kamenice 753/5, Pavilon A29, 625 00 Brno, Czech Republic
- ^dAquatic Ecology & Toxicology, COS – Center for Organismal Studies, University of Heidelberg, Im Neuenheimer Feld 230, 69120 Heidelberg, Germany
- ^eECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals), Avenue E. Van Nieuwenhuysse Building 2, 3rd Floor, Bte 8 1160 Brussels, Belgium
- ^fEawag, Swiss Federal Institute of Aquatic Science and Technology, Department Environmental Toxicology, Überlandstrasse 133, P.O. Box 611, 8600 Dübendorf, Switzerland
- ^gEPF Lausanne, School of Architecture, Civil and Environmental Engineering, 1015 Lausanne, Switzerland
- ^hETH Zürich, Department of Environmental Systems Science, 8092 Zürich, Switzerland
- ⁱWIL Research Europe B.V., Hambakenwetering 7, 5231 DD 's-Hertogenbosch, The Netherlands
- ^jFlemish Institute for Technological Research (Vito), Environmental Risk & Health, Team Applied Bio & Molecular Systems (ABS) Boeretang 200, Mol 2400, Belgium
- ^kThe Procter & Gamble Company, Global Product Stewardship, 8700 Mason Montgomery Road, Mason, OH 45040, United States
- ^lIRCCS – Istituto di Ricerche Farmacologiche, “Mario Negri” Laboratory of Environmental Chemistry and Toxicology, Via La Masa 19, 20156 Milano, Italy
- ^mNational Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), Gibbs Building, 215 Euston Road, London NW1 2BE, United Kingdom
- ⁿLiverpool John Moores University, School of Pharmacy and Biomolecular Sciences, Byrom Street, Liverpool L3 3AF, United Kingdom
- ^oEawag, Swiss Federal Institute of Aquatic Science and Technology, Überlandstrasse 133, P.O. Box 611, 8600 Dübendorf, Switzerland
- ^pILSI Health and Environmental Sciences Institute (HESI), 1156 15th Street, NW, 2nd floor, Washington, DC 20005, United States
- ^qU.S. Environmental Protection Agency, Ecosystems Research Division, National Exposure Research Laboratory, Office of Research and Development, 960 College Station Road, Athens, GA 30605-2700, United States
- ^rOrganisation for Economic Co-operation and Development (OECD), 2 Rue André Pascal, 75016 Paris, France
- ^sEuropean Commission Joint Research Centre, Institute for Health and Consumer Protection, EURL ECVAM, Via E. Fermi 2749, 21027 Ispra (Varese), Italy
- ^tDouglas Connect, Bärmeggenweg 14, 4314 Zeiningen, Switzerland
- ^uJohns Hopkins University, Bloomberg School of Public Health, CAAT, 615 N. Wolfe Street, Baltimore, MD 21205, United States
- ^vCEFIC – The European Chemical Industry Council, 4 Avenue E. Van Nieuwenhuysse, 1160 Brussels, Belgium
- ^wTechnische Universität Dresden, Fakultät Umweltwissenschaften, Institut für Hydrobiologie, 01062 Dresden, Germany
- ^xExxonMobil Petroleum and Chemical, Hermeslaan 2, 1831 Machelen, Belgium
- ^yDepartment of Biology, University of the Fraser Valley, Abbotsford, BC, Canada
- ^zL'ORÉAL Research and Innovation, Environmental Research Department, 1 Avenue Eugène Schueller, 93601 Aulnay sous Bois, France
- ^{aa}Norwegian Institute for Water Research (NIVA), Gaustadalléen 21, 0349 Oslo, Norway
- ^{ab}Wageningen University, Environmental Technology Department and Wageningen IMARES: Institute for Marine, Resources and Ecosystem Studies, P.O. Box 17, 6700 AA Wageningen, The Netherlands
- ^{ac}National Institute for Agricultural and Food Research and Technology (INIA), Department of Environment, Ctra. de la Coruña Km 7.5, E-28040 Madrid, Spain
- ^{ad}RIVM, Center for Substances and Products, P.O. Box 1, 3720 BA Bilthoven, The Netherlands
- ^{ae}University of Leiden, Center for Environmental Sciences (CML), Leiden, The Netherlands
- ^{af}University Pablo de Olavide, Area of Toxicology, Dep. Biología Molecular e Ingeniería, Bioquímica, Ctra. de Utrera Km 1, 41013 Sevilla, Spain
- ^{ag}Experimental Toxicology and Ecology (GV/TC), BASF SE, GV/TC – Z570, 67056 Ludwigshafen, Germany
- ^{ah}UFZ – Helmholtz Centre for Environmental Research, Department of Ecological Chemistry, 04318 Leipzig, Germany
- ^{ai}Institute for Organic Chemistry, Technical University Bergakademie Freiberg, Leipziger Straße 29, 09596 Freiberg, Germany
- ^{aj}Faculty of Biology, Chemistry, Pharmacy, Freie Universität Berlin, Kaiserswerther Street 16–18, 14195 Berlin, Germany
- ^{ak}Federal Environment Agency (UBA), International Chemical Management, P.O. Box 1, 406 06813 Dessau-Roßlau, Germany
- ^{al}Shell Health, Shell Technology Centre, Thornton, P.O. Box 1, Chester CH13SH, United Kingdom
- ^{am}Environmental Safety, Syngenta Ltd., Jealott's Hill International Research Centre, Bracknell Berkshire RG42 6EY, United Kingdom
- ^{an}Brixham Environmental Laboratory, AstraZeneca UK Ltd., Freshwater Quarry, Brixham, Devon TQ5 8BA, United Kingdom

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ABSTRACT

Tests with vertebrates are an integral part of environmental hazard identification and risk assessment of chemicals, plant protection products, pharmaceuticals, biocides, feed additives and effluents. These tests raise ethical and economic concerns and are considered as inappropriate for assessing all of the substances and effluents that require regulatory testing. Hence, there is a strong demand for replacement, reduction and refinement strategies and methods. However, until now alternative approaches have only rarely been used in regulatory settings. This review provides an overview on current regulations of chemicals and the requirements for animal tests in environmental hazard and risk assessment. It aims to highlight the potential areas for alternative approaches in environmental hazard identification and risk assessment. Perspectives and limitations of alternative approaches to animal tests using vertebrates in environmental toxicology, i.e. mainly fish and amphibians, are discussed. Free access to existing (proprietary) animal test data, availability of validated alternative methods and a practical implementation of conceptual approaches such as the Adverse Outcome Pathways and Integrated Testing Strategies were identified as major requirements towards the successful development and implementation of alternative approaches. Although this article focusses on European regulations, its considerations and conclusions are of global relevance.

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1. Introduction

Animal tests are an integral part of environmental hazard identification and risk assessment of industrial chemicals, plant protection products, biocides, feed additives and pharmaceuticals. They are also used to monitor the quality of effluents and surface waters to improve the assessment of the status of European waters under the auspices of the Water Framework Directive (EU, 2000). Depending on intended use, diverse regulations are applied that

require different types of animal tests. This has raised ethical concerns with regard to tests using vertebrates in environmental risk assessment (mainly fish, amphibians, and birds; occasionally, mammals are used, for example for testing of rodenticides and plant protection products, EU, 2013, 2012c). Ethical concerns – according to European regulation (EU, 2010a) – apply also to cephalopods, but these are not commonly used in environmental risk assessment. Even though many regulatory frameworks principally encourage the use of alternative approaches such as

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