

Curriculum Vitae

Last name, First name: ...Bernauer, Ulrike

Gender: Female

Nationality: German

Overall Scientific Expertise:

- > 20 Years experience in risk assessment of chemicals (focus human/consumer safety)
- Risk assessment of cosmetic ingredients (SCCS)
- Hazard and risk assessment of chemicals in REACH-relevant processes (evaluation, SVHC identification, classification and labelling)
- Development of toxicological test guidelines and guidance documents (OECD, REACH)
- Participation in national and international programs in the context of consumer safety (e.g. human biomonitoring)
- Contribution to political decision making for certain compounds (e.g. phthalates, perfluorinated compounds).
- Workplace safety
- Regulatory toxicology
- Metabolism and toxicokinetics
- Research related to chemical safety
- Alternative and non-testing strategies
- Nanotoxicology

Professional Experience

Years employed from – to	Title of position	Employer – name and location	Areas of professional specialisation*
Since 2012	Deputy Head of Unit Chemicals Safety	Federal Institute for Risk Assessment (BfR), Berlin, Germany	Risk assessment of new and existing chemicals, implementation of REACH, assessment of chemicals under REACH Metabolism, Toxicokinetics
Since 2004	Scientific employee/scientific civil servant	Federal Institute for Risk Assessment (BfR), Berlin, Germany	Risk assessment of new and existing chemicals, implementation of REACH, assessment of chemicals under REACH
10/1997 – 12/2003	Scientific employee	Federal Institute for Risk Assessment (BfR) (formerly called BgVV)	Responsibility for research projects related to risk assessment of chemicals (intra- and interspecies variability of metabolising enzymes; <i>in vitro</i> methods (genetically modified

			cells), extrahepatic metabolism, instrumental analytics)
08/1996 – 09/1997	Scientific employee (Postdoctorate)	University of Wurzburg, Department Toxicology	Interspecies comparison of the biotransformation of fuel additives (MTBE, ETBE and TAME) between rats and humans (metabolism, toxicokinetics, GC- and HPLC analytics)

Year	Degree awarded	Educational Institution – name and location	Areas of educational specialisation*
1996-1996		Postdoctorate, University of Wurzburg, Germany (Department of Toxicology)	Xenobiotic metabolism, analytical toxicology
1993 - 1996	Dr. rer. nat.	Doctorate, University of Wurzburg (Department of Toxicology)	Biochemical and analytical toxicology, biomarkers, protein biochemistry, enzymology
1987-1993	Dipl. Chem.	University of Wurzburg, Department of Chemistry (Diploma thesis performed at the department of toxicology) Chemistry studies	Organic chemistry, physical chemistry, inorganic chemistry, biochemistry, toxicology, physics, mathematics

Memberships in Scientific Advisory Bodies/Committees/Panels:

Scientific Committee for Consumer Safety (SCCS), 2009 – present

Chair of the SCCS Working Group on Nanomaterials in Cosmetics (since 2016)

UAIII of the AGS (Panel on hazardous chemicals of the German Federal Ministry of Labour and Social Affairs), 2010 – present

German “Expertenkreis Humanbiomonitoring” (Body of experts for human biomonitoring) of the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, 2010 – present

Member of past and present expert groups of the OECD Testguideline program

Reserve list of Scientific Experts for Scientific Panels and the Contam Panel of the European Food Safety Authority, since 2015

Expert database of ECHA (European Chemicals Agency)

Memberships in Learned Societies:

Member of the EUROTOX Risk Assessment Specialty Group

Teaching Activities

- DGK Cosmetic Science: Training Courses for Safety Assessors
- Apothekerkammer Berlin: Toxicological Training for Pharmacists
- Vrije Universiteit Brussels: International Training Course on Safety assessment of Cosmetics in the EU
- Fresenius Academy

Memberships in Editorial Boards (*if any*):

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List of Publications:

Predominantly SCCS opinions and unpublished reports prepared in the context of REACH and CLP regulation

- > 30 Scientific Publications in peer-reviewed journals (first-author in 10 publications)
- 2 Research reports concerning xenobiotic metabolism
- 3 book chapters
- publications in non-peer-reviewed journals
- Co-author of EFSA/ OECD publications
- Several Poster / Conference Abstracts

Bibliographic details for the 7 most representative, published, peer-reviewed reports:

Adler, S., Basketter, D., Creton, S., Pelkonen, O., van Benthem, J., Zuang, V., Andersen, K.E., Angers-Loustan, A., Aptula, A., Bal-Price, A., Benfanti, E., **Bernauer, U.** et al (2011): Alternative (non-Animal) methods for cosmetics testing: current status and future prospects – 2010. Arch. Toxicol. 85, 367-485.

Coecke, S., Pelkonen, O., Leite, S.B., **Bernauer, U.**, Bessems, J., Bois, F.Y., Ursula Gundert-Remy, U., Loizou, G., Testai, E., Zaldívar, J.M. (2013): Toxicokinetics as a key to the integrated toxicity risk assessment based primarily on non-animal approaches. Toxicology in Vitro 27, 1570 – 1577.

Gundert-Remy, U., **Bernauer, U.**, Blömeke, B., Döring, B., Fabian, E., Goebel, C., Hessel, S., Jäckh, C., Lampen, A., Oesch, F., Petzinger, E., Völkel, W. and Roos, P.H. (2014): Extrahepatic metabolism at the body's internal-external interfaces. Drug. Metab. Rev. 46, 291 – 324.

Jacobs, M.N., Janssens, W., **Bernauer, U.**, Brandon, E., Coecke, S., Combes, R., Edwards, P., Freidig, A., Freyberger, A., Kolanczyk, R., McArdle, C., Mekyan, O., Schmieder, P., Schrader, T., Tekeyoshi, M., and van der Burg, B. (2008): The use of metabolising systems for in vitro testing of endocrine disruptors, Current Drug Metabolism 9, 796 - 826.

Bernauer, U., Heinemeyer, G., Heinrich-Hirsch, B., Ulbrich, B. and Gundert-Remy, U. (2008): Exposure-triggered reproductive toxicity testing under the REACH legislation: A proposal to define significant/relevant exposure. Toxicol. Lett. 176, 68 – 76.

Bernauer, U., L. Bodin, Q. Chaudhry, P. Coenraads, M. Dusinska, E. Gaffet, I. Panderi, V. Rogiers, C. Rousselle, M. Stepnik, T. Vanhaecke, S. Wijnhoven, N. Goetz, W. De Jong, and A. Simonnard, 2020, The

SCCS guidance on the safety assessment of nanomaterials in cosmetics. Regulatory Toxicology and Pharmacology. 112: p. 104611.

Rogiers, V., E. Benfenati, **U. Bernauer**, L. Bodin, P. Carmichael, Q. Chaudhry, P.J. Coenraads, M.T.D. Cronin, M. Dent, M. Dusinska, C. Ellison, J. Ezendam, E. Gaffet, C.L. Galli, C. Goebel, B. Granum, H.M. Hollnagel, P.S. Kern, K. Kosemund-Meynen, G. Ouédraogo, E. Panteri, C. Rousselle, M. Stepnik, T. Vanhaecke, N. von Goetz, and A. Worth, 2020, The way forward for assessing the human health safety of cosmetics in the EU - Workshop proceedings. Toxicology. 436: p. 152421.

Other

Risk Governance of Advanced Materials

Considerations from the joint perspective of the German Higher Federal Authorities BAuA, BfR and UBA

by:Kathrin Schwirn, Doris Völker

German Environment Agency, Dessau-RoßlauAndrea Haase, Jutta Tentschert, **Ulrike Bernauer** German Federal Institute for Risk Assessment, Berlin Rolf Packroff, Volker Bachmann
Federal Institute for Occupational Safety and Health, Dortmund and Berlin

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2022

Bernauer, U., L. Bodin, Q. Chaudhry, P.J. Coenraads, M. Dusinska, J. Ezendam, E. Gaffet, C.L. Galli, B. Granum, E. Panteri, V. Rogiers rapporteur, C. Rousselle, M. Stepnik, T. Vanhaecke, S. Wijnhoven, A. Koutsodimou, W. Uter, and N. von Goetz, 2021, The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 11th revision, 30–31 March 2021, SCCS/1628/21. *Regulatory Toxicology and Pharmacology*. 127: p. 105052.

<https://www.sciencedirect.com/science/article/pii/S0273230021001938>

<https://doi.org/10.1016/j.yrtph.2021.105052>

21. Bernauer, U., L. Bodin, Q. Chaudhry, P.J. Coenraads, M. Dusinska, E. Gaffet, E. Panteri, V. Rogiers, C. Rousselle, M. Stepnik, T. Vanhaecke, S. Wijnhoven, N. von Goetz, and W.H. de Jong, 2021, The SCCS scientific advice on the safety of nanomaterials in cosmetics. *Regulatory Toxicology and Pharmacology*. 126: p. 105046.

<https://www.sciencedirect.com/science/article/pii/S0273230021001872>

<https://doi.org/10.1016/j.yrtph.2021.105046>

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Risk Governance of Advanced Materials

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<https://www.umweltbundesamt.de/publikationen/risk-governance-of-advanced-materials>

2020

Bernauer, U., L. Bodin, Q. Chaudhry, P. Coenraads, M. Dusinska, E. Gaffet, I. Panderi, V. Rogiers, C. Rousselle, M. Stepnik, T. Vanhaecke, S. Wijnhoven, N. Goetz, W. De Jong, and A. Simonnard, 2020, The SCCS guidance on the safety assessment of nanomaterials in cosmetics. *Regulatory Toxicology and Pharmacology*. 112: p. 104611.

Rogiers, V., E. Benfenati, U. Bernauer, L. Bodin, P. Carmichael, Q. Chaudhry, P.J. Coenraads, M.T.D. Cronin, M. Dent, M. Dusinska, C. Ellison, J. Ezendam, E. Gaffet, C.L. Galli, C. Goebel, B. Granum, H.M. Hollnagel, P.S. Kern, K. Kosemund-Meynen, G. Ouédraogo, E. Panteri, C. Rousselle, M. Stepnik, T. Vanhaecke, N. von Goetz, and A. Worth, 2020, The way forward for assessing the human health safety of cosmetics in the EU - Workshop proceedings. *Toxicology*. 436: p. 152421.

2019

Bernauer, U., Bodin, L., Celleno, L., Chaudhry, Q., Coenraads, P., Dusinska, M., Duus-Johansen, J., Ezendam, J., Gaffet, E., Galli, L., Granum, B., Panteri, E., Rogiers, V., Rousselle, C., Stepnik, M., Vanhaecke, T., Wijnhoven, S., Koutsodimou, A., Simonnard, A., and Uter, W., 2019, Opinion of the Scientific Committee on consumer safety (SCCS) - Opinion on Ethylzingerone – ‘Hydroxyethoxyphenyl Butanone’ (HEPB). *Regulatory Toxicology and Pharmacology*. 107: 104393
Impact Factor/2018: 3

6. Bernauer, U., Bodin, L., Chaudhry, Q., Coenraads, P., Dusinska, M., Ezendam, J., Gaffet, E., Galli, L., Granum, B., Panteri, E., Rogiers, V., Rousselle, C., Stepnik, M., Vanhaecke, T., Wijnhoven, S., Koutsodimou, A., Simonnard, A., and Uter, W., 2019, Opinion of the Scientific Committee on Consumer safety (SCCS) – Opinion on the safety of cosmetic ingredient salicylic acid (CAS 69-72-7). *Regulatory Toxicology and Pharmacology*. 108: 104376

Impact Factor/2018: 3

7. Bernauer, U., Bodin, L., Chaudhry, Q., Coenraads, P., Dusinska, M., Ezendam, J., Gaffet, E., Galli, L., Granum, B., Panteri, E., Rogiers, V., Rousselle, C., Stępnik, M., Vanhaecke, T., Wijnhoven, S., Koutsodimou, A., Simonnard, A., and Uter, W., 2019, Opinion of the Scientific Committee on consumer safety (SCCS) – Final opinion on the safety of fragrance ingredient Acetylated Vetiver Oil (AVO) - (Vetiveria zizanioides root extract acetylated) - Submission III. Regulatory Toxicology and Pharmacology. 107: 104389

Impact Factor/2018: 3

De Jong, W.H., Bertolini, R., Borges, T., De Jong, W., de Voogt, P., Duarte-Davidson, R., Hoet, P., Ion, R.M., Kraetke, R., Panagiotakos, D., Proykova, A., Samaras, T., Scott, M., Slama, R., Testai, E., Vermeire, T., Vighi, M., Zacharo, S., Bernauer, U., Rouselle, C., Bégué, S., Kopperud, H.M., Milana, M.R., and Schmidt, T., 2019, Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties. Regulatory Toxicology and Pharmacology. 111

Mech, A., Rasmussen, K., Jantunen, P., Aicher, L., Alessandrelli, M., Bernauer, U., Bleeker, E.A.J., Bouillard, J., Di Prospero Fanghella, P., Draisci, R., Dusinska, M., Encheva, G., Flament, G., Haase, A., Handzhiyski, Y., Herzberg, F., Huwyler, J., Jacobsen, N.R., Jeliazkov, V., Jeliazkova, N., Nymark, P., Grafström, R., Oomen, A.G., Polci, M.L., Riebeling, C., Sandström, J., Shivachev, B., Stateva, S., Tanasescu, S., Tsekovska, R., Wallin, H., Wilks, M.F., Zellmer, S., and Apostolova, M.D., 2019, Insights into possibilities for grouping and read-across for nanomaterials in EU chemicals legislation. Nanotoxicology. 13(1): 119-141

2018

Scientific Committee of Consumer Safety - SCCS, Bernauer, U., 2018. Opinion of the Scientific Committee on Consumer Safety (SCCS) - Revision of the Opinion on hydroxyapatite (nano) in cosmetic products. Regulatory Toxicology and Pharmacology, 98: 274-275.

Impact Factor/2017: 3

<https://reader.elsevier.com/reader/sd/1AEF7787C5EE4AB4BFA47418F951664B986EFDF2D159F0A4B7FB348C19B4A9F17408065A801E4DF82C98B32002ADD0F2>

2017

Bernauer, U., 2017. Opinion of the scientific committee on consumer safety (SCCS) - Final version of the opinion on Ethylzingerone - 'Hydroxyethoxyphenyl Butanone' (HEPB) - Cosmetics Europe No P98 - in cosmetic products. Regulatory Toxicology and Pharmacology, 88: 330-331.

2016

Bernauer, U., 2017. Opinion of the scientific committee on consumer safety (SCCS) - Final version of the opinion on Ethylzingerone - 'Hydroxyethoxyphenyl Butanone' (HEPB) - Cosmetics Europe No P98 - in cosmetic products. Regulatory Toxicology and Pharmacology, 88: 330-331.

Testai, E., Ms Scientific Committee SCENIHR, Hartemann, P., Rastogi, S. C., Bernauer, U., Piersma, A., De Jong, W., Gulliksson, H., Sharpe, R., Schubert, D., Rodriguez-Farre, E., 2016. The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update). Regulatory Toxicology and Pharmacology, 76: 209-210.

Impact Factor: 2

2015

Testai, E., Ms Scientific Committee SCENIHR, Hartemann, P., Rastogi, S. C., Bernauer, U., Piersma, A., De Jong, W., Gulliksson, H., Sharpe, R., Schubert, D., Rodriguez-Farre, E., 2016. The safety of medical

devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update). *Regulatory Toxicology and Pharmacology*, 76: 209-210.

Impact Factor: 2

Scientific Committee on Consumer Safety (SCCS), Bernauer, U., 2015. Opinion of the scientific committee on consumer safety (SCCS) - 2nd Revision of the safety of the use of poly(hexamethylene) biguanide hydrochloride or polyaminopropyl biguanide (PHMB) in cosmetic products. *Regulatory Toxicology and Pharmacology*, 73(3): 885–886.

Impact Factor/2014: 2.031