

# Abbreviations and References - Handbook 2021 Workshop

## In this guide

### [In this guide](#)

1. [Handbook Cover Page - 2021 Workshop](#)
2. [Handbook table of contents - 2021 Workshop](#)
3. [Introduction - Handbook 2021 Workshop](#)
4. [Preface and workshop objectives - Handbook 2021 Workshop](#)
5. [PBPK for Regulators Workshop agenda 2nd December 2020 - Handbook 2021 Workshop](#)
6. [Introduction to physiologically based pharmacokinetic \(PBPK\) modelling - Handbook 2021 Workshop](#)
7. [In emerging approaches - Handbook 2021 Workshop](#)
8. [Current regulatory landscape - Handbook 2021 Workshop](#)
9. [Questions put forward for the discussion sessions - Handbook 2021 Workshop](#)
10. [Speakers biosketches - Handbook 2021 Workshop](#)
11. [COT Members and Secretariat - Handbook 2021 Workshop](#)
12. [Abbreviations and References - Handbook 2021 Workshop](#)

## Abbreviations

ADME      Absorption, Distribution, Metabolism and Excretion

AOP        Adverse Outcome Pathway

ATSDR     Agency for Toxic Substances and Disease Registry

BMDL	Benchmark Dose Level
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
DDI	Drug-drug interaction
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EURL- ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
FSA	Food Standards Agency
HBM	Human Biomonitoring
HESI	Health and Environmental Sciences Institute
Httk	High-Throughput Toxicokinetics
ICF	IndusChemFate
ICH	International Council for Harmonisation
ILSI	International Life Sciences Institute
IMED	Innovative Medicines

IPCS	International Programme on Chemical Safety
ISI	The Institute for Scientific Information
JECFA	Joint Food and Agriculture Organisation/World Health Expert Committee on Food Additives
JMPR	Joint Food and Agriculture Organisation/World Health Expert Committee on Pesticide Residues
LJMU	Liverpool John Moores University
MoA	Mode of Action
NAMs	New Approach Methodologies
NOAEL	No-observed-adverse-effect-level
OECD	Organisation for Economic Cooperation and Development OSHA
OECD	Organisation for Economic Cooperation and Development OSHA
PBPK	Physiologically based Pharmacokinetic Modelling
PFOA	Perfluorooctanoic acid
(Q)SAR	(Quantitative-) Structure Activity Relationship SERD
TD	Toxicodynamic
TK	Toxicokinetic

US EPA United States Environmental Protection Agency US FDA

TD Toxicodynamic

WHO World Health Organisation

## References

Andersen, M. E., Clewell III, H. J., Gargas, M. L., Smith, F. A. and Reitz, R. H. (1987) Physiologically based pharmacokinetics and the risk assessment process for methylene chloride. *Toxicology and Applied Pharmacology* 87(2), pp. 185-205.

Bossier, H., Chau, J., Ndour, C., Varewyck, M., Verbeke, T. and Vergucht, S. (2020) A Web-based open source tool for Toxicokinetic and Toxicodynamic modelling. EFSA Supporting Publication: EN-1926. Available at: [A Web-based open source tool for Toxicokinetic and Toxicodynamic modelling | EFSA \(europa.eu\)](#). Accessed: 17/11/2020.

IPCS. (2005) Principles of characterizing and applying human exposure models. Geneva, World Health Organisation, International Programme on Chemical Safety. Harmonisation Project Document No. 3; pp.67. Available at: [Principles of characterizing and applying human exposure models \(who.int\)](#) Accessed: 28/10/2020.

OECD. (2005) Guidance document on the validation and international acceptance of new or updated test methods for hazard assessment. OECD Series on Testing and Assessment Number 34. [OECD Guidance Document 34: Validation and International Acceptance of New or Updated Internationally Acceptable Test Methods for Hazard Assessment \(nih.gov\)](#) Accessed: 17/11/2020.

Paini, A., Leonard, J. A., Kliment, T., Tan, Y-M. and Worth, A. (2017) Investigating the state of physiologically based kinetic modelling practices and challenges associated with gaining regulatory acceptance of model applications. *Regulatory Toxicology and Pharmacology* 90, pp. 104-115.

Parish, S. T., Aschner, M., Casey, W., Corvaro, M., Embry, M. R., Fitzpatrick, S., Kidd, D., Kleinstreuer, N. C., Lima, B, S., Settivari, R. S., Wolf, D. C., Yamazaki, D. and Boobis, A. (2020) An evaluation framework for new approach methodologies (NAMs) for human health safety assessment. *Regulatory Toxicology and*

Pharmacology 111, 104592.

Pletz, J., Blakeman, S., Paini, A., Parissis, N., Worth, A., Andersson, A-M., Frederiksen, H., Sakhi, A. K., Thomsen, C. and Bopp, S. K. (2020) Physiologically based kinetic (PBK) modelling and human biomonitoring data for mixture risk assessment. *Environment International* 143, 105978.

Rietjens, I. M. C. M., Louisse, J. and Punt, A. (2011) Tutorial on physiologically based kinetic modelling in molecular nutrition and food research. *Molecular Nutrition and Food Research* 55(6), pp. 941-956.

Sager, J. E., Yu, J., Ragnuneneau-Majlessi, I. and Isoherran, N. (2015) Physiologically based pharmacokinetic (PBPK) modelling and simulation approaches: A systematic review of published models, applications, and model verification. *Drug Metabolism and Disposition* 34; pp. 1823-1837.

Tan, Y-M., Chan, M., Chukwudebe, A., Domoradzki, J., Fisher, J., Hack, C. E., Hinderliter, P., Hirasawa, K., Leonard, J., Lumen, A., Paini, A., Qian, H., Ruiz, P., Wambaugh, J., Zhang, F. and Embry, M. (2020) PBPK Model reporting template for chemical risk assessment applications. *Regulatory Toxicology and Pharmacology* 115, 104691.

Teorell, T. (1937) Kinetics of distribution of substances administered to the body. I & II. *Archives internationales de pharmacodynamie et de therapie* 57, pp. 205-240. ISSN 0003-9780.

US EPA. (2006) Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment (Final Report). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-05/043F, 2006: [Approaches For the Application of Physiologically Based Pharmacokinetic \(PBPK\) Models and Supporting Data In Risk Assessment \(Final Report\) | Risk Assessment Portal | US EPA](#) Accessed: 28/10/2020.

WHO. (2010) Guidance on principles of characterizing and applying PBPK models in risk assessment: [Characterization and application of physiologically based pharmacokinetic models in risk assessment \(who.int\)](#) Accessed: 26/10/2020.