

References - 2021 Workshop Report

In this guide

[In this guide](#)

1. [COT FSA PBPK for Regulators Workshop Report 2021 - Cover page](#)
2. [Summary - COT FSA PBPK for Regulators Workshop Report 2021](#)
3. [Background - COT FSA PBPK for Regulators Workshop Report 2021](#)
4. [UK Food Standards Agency \(FSA\) requirement for PBPK modelling - 2021](#)
5. [Objectives and outline of the workshop - 2021](#)
6. [Questions put forward for the discussion sessions - 2021](#)
7. [Presentations and Panel discussions - 2021 Workshop report](#)
8. [Overarching conclusions - 2021 Workshop Report](#)
9. [Technical Terms - 2021 Workshop Report](#)
10. [Abbreviations - 2021 Workshop Report](#)
11. [References - 2021 Workshop Report](#)
12. [Organizing Committee, Committee Members and COT Secretariat - 2021 Workshop Report](#)

Blancato, J. N. and Rhomberg, L. (1988) The Impact of Pharmacokinetics on the Risk Assessment of Dichloromethane. US Environmental Protection Agency, Office of Research and Development, Office of Health and Environmental Assessment: [IMPACT OF PHARMACOKINETICS ON THE RISK ASSESSMENT OF DICHLOROMETHANE | Risk Assessment Portal | US EPA](#)

Berkley Madonna Website: [Berkeley Madonna \(berkeley-madonna.myshopify.com\)](http://berkeley-madonna.myshopify.com)

Bois, F.Y. and Maszle, D.R., 1997. MCSim: a Monte Carlo simulation program. Journal of Statistical Software, 2, pp.1-60.

Clewell, H. J., Gentry, P. R., Gearhart, J. M., Allen, B. C. and Andersen, M. E. (2001) Comparison of cancer risk estimates for vinyl chloride using animal and human data with a PBPK model. Science of the Total Environment 274, pp.37-66.

COT Working Paper On Physiologically Based Pharmacokinetic Modelling
Version 1: [\[ARCHIVED CONTENT\] \(nationalarchives.gov.uk\)](#)

COT Statement on physiologically based pharmacokinetic modelling (2023)
[\[ARCHIVED CONTENT\] Statement on physiologically based pharmacokinetic modelling | Food Standards Agency \(nationalarchives.gov.uk\)](#)

COT statement on the COT workshop on evolving approaches to chemical risk assessment: [\[ARCHIVED CONTENT\] COT statement on the COT workshop on evolving approaches to chemical risk assessment | Food Standards Agency \(nationalarchives.gov.uk\)](#)

COT statement on the COT workshop on 21st century toxicology:
[\[ARCHIVED CONTENT\] COT statement on the COT workshop on 21st century toxicology | Food Standards Agency \(nationalarchives.gov.uk\)](#)

COT Discussion Paper TOX 2019 34 -Review of physiologically-based pharmacokinetic (PBPK) modelling used for human health risk assessment: [Tox-2019-34 PBPK \(food.gov.uk\)](#)

COT Discussion Paper Case studies: applications of physiologically-based pharmacokinetic (PBPK) modelling in human health risk assessment:
[tox201973pbpkcasesstudies \(food.gov.uk\)](#)

EFSA. (2014) Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products:
[Good modelling practice | EFSA \(europa.eu\)](#)

El-Khateeb, E., Burkhill, S., Murby, S., Amirat, H., Rostami-Hodjegan, A. and Ahmad, A., 2021. Physiological-based pharmacokinetic modeling trends in pharmaceutical drug development over the last 20-years; in-depth analysis of applications, organizations, and platforms. *Biopharmaceutics & Drug Disposition*, 42(4), pp.107-117.

EMA. (2018) Reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation: [Reporting of physiologically based pharmacokinetic \(PBPK\) modelling and simulation - Scientific guideline | European Medicines Agency \(europa.eu\)](#)

INTEGRA Website: [INTEGRA – Integrated External and Internal Exposure Modelling Platform – Cefic-Lri](#)

Japanese PMDA. (2020) Guidelines on the use of PBPK model simulations for drug development: [000239317.pdf \(pmda.go.jp\)](https://www.pmda.go.jp/files/000239317.pdf)

Magnolia Website: [Magnolia - Software for Mathematical Modeling and Simulation \(magnoliasci.com\)](https://magnoliasci.com)

Meek, M. B., Barton, H. A., Bessems, J. G., Lipscomb, J. C. and Krishnan, K. (2013) Case study illustrating the WHO IPCS guidance on characterization and application of physiologically based pharmacokinetic models in risk assessment. *Regulatory Toxicology and Pharmacology* 66, pp.116-129.

Mielke, H., Abraham, K., Götz, M., Vieth, B., Lampen, A., Luch, A. and Gundert-Remy, U. (2011) Physiologically based toxicokinetic modelling as a tool to assess target organ toxicity in route-to-route extrapolation - The case of coumarin. *Toxicology Letters* 202, pp. 100-110.

National Research Council. 2007. Toxicity Testing in the 21st Century: A Vision and a Strategy. Washington, DC: The National Academies Press: [Toxicity Testing in the 21st Century: A Vision and a Strategy | The National Academies Press](https://www.nationalacademies.org/pubs/toxicity-testing-in-the-21st-century-a-vision-and-a-strategy/)

OECD Guidance document on the characterisation, validation and reporting of PBK modes for regulatory purposes (2021): [Guidance document on the characterisation, validation and reporting of Physiologically Based Kinetic \(PBK\) models for regulatory purposes \(oecd.org\)](https://www.oecd.org/chemicalsafety/guidance-document-on-the-characterisation-validation-and-reporting-of-physiologically-based-kinetic-pbk-models-for-regulatory-purposes/)

Paini, A., Joossens, E., Bessems, J., Desalegn, A., Dorne, J-L., Gosling, J. P., Heringa, M. B., Klaric, M., Kramer, N., Loizou, G., Louise, J., Lumen, A., Madden, J. C., Patterson, E. A., Proença, S., Punt, A., Setzer, R. W., Suci, N., Troutman, J., Yoon, M., Worth, A. and Tan, Y. M. (2017) EURL ECVAM Workshop on new generation of physiologically-based kinetic models in risk assessment. EUR 28794 EN, Publications Office of the European Union, Luxembourg. ISBN 978-92-79-73849-4, <http://dx.doi.org/10.2760/619902>

Pendse, S. N., Efremenko, A., Hack, C. E., Moreau, M., Mallick, P., Dzierlenga, M., Nicolas, C. I., Yoon, M., Clewell, H. J. and McMullen, P. D. (2020) Population Life-course exposure to health effects model (PLETHEM): An R package for PBPK modelling. *Computational Toxicology* 13, 100115.

Pletz, J. (2021) A mechanistic model to study the kinetics and toxicity of salicylic acid in the kidney of four virtual individuals. *Computational Toxicology* (Under review).

RVis – Open Access PBPK Modelling Platform:[AIMT7: RVis – Open Access PBPK Modelling Platform – Cefic-Lri](#)

SCCS. (2016) Opinion on decamethylcyclopentasiloxane (cyclopentasiloxane, D5) in cosmetic products: [Opinion of the Scientific Committee on Consumer Safety on o-aminophenol \(A14\) \(europa.eu\)](#)

SCCS. (2018) The SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation 10th revision:[8d49f487-909c-4498-af89-1f769aaa628c_en \(europa.eu\)](#)

Sympcyp: [Certara Simcyp™ PBPK Simulator | Predicting Drug Performance](#)

Tan, Y-M., Worley, R. R., Leonard, J. A. and Fisher, J.W. (2018) Challenges associated with applying physiologically based pharmacokinetic modeling for public health decision-making. Toxicological Sciences 162, pp.341-348.

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.

US FDA. (2018) Physiologically based pharmacokinetic analyses – Format and content Guidance for Industry: [Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry \(fda.gov\)](#)

WHO & IPCS. (2010) Characterisation and application of physiologically based pharmacokinetic models in risk assessment: [Characterization and application of physiologically based pharmacokinetic models in risk assessment \(who.int\)](#)