

PBPK for Regulators Workshop Summary - NAMS Roadmap (2023)

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The UK FSA and the COT held a “PBPK for Regulators” workshop (December 2020) in a multidisciplinary setting with delegates from regulatory agencies, government bodies, academia and industry. The workshop provided a platform to

enable expert discussions and presentations on the application of PBPK to human health risk assessment in a regulatory context as well as potential future research.

Main overarching conclusions of the PBPK workshop:

- a) PBPK modelling tools are applicable in the explored areas of use, and there is some expertise available for their utilisation.
- b) PBPK modelling offers opportunities from which to address questions for compounds that are otherwise not solvable.
- c) Widespread acceptance amongst regulatory bodies appears to be limited by lack of available in-house expertise.
- d) Familiarisation using real world case studies would help in developing more experts in the field and increasing acceptance.
- e) In a regulatory context, establishing fitness for purpose for the use of PBPK models require multi-partite discussion and harmonised guidance.
- f) Finally, PBPK modelling is part of the wider “new approach methodologies” for risk assessment.

Paving the way for a UK Roadmap-Development, Validation and Acceptance of New Approach Methodologies Workshop summary

The UK FSA and the COT held a workshop that took place online over 2 days in October 2021. It had participation from industry, academics and regulators. The aim of the workshop was to receive insights, comments and input from a wide variety of stakeholders and industry, academia and government, on the roadmap so that it can be developed and a useful and engaging document produced, that is beneficial to more than just the FSA and COT. This included a range of scientists, policy and lawyers, and working in the international space and engaging with the public. Furthermore, there were discussions on what is holding the progress back including a range of areas such as law, economics, socio-technical barriers and regulatory frameworks.