

Using new approach methodologies in regulatory science: tools and methods for integration of evidence

George FOTAKIS
European Chemicals Agency, Helsinki, Finland

The presentation will focus on a review of available methodologies and tools that can facilitate the integration of evidence derived with new approach methodologies. Such methodologies vary in terms of complexity and range from general schemas/frameworks consisting of sets of questions to more elaborate approaches. The choice of the methodology used for integration of evidence is interrelated to the communication needs, goals and degree of confidence required set within the problem formulation.

An overview of existing and current work from WHO/IPCS, the OECD, the European Commission's scientific committees, ECHA and other regulatory institutions regarding integration of evidence approaches will be provided.

In addition, the presentation will include an overview of terminology used in the field of integration of evidence, in particular regarding weight of evidence and confidence/uncertainty.

The relevance of the methodologies with practical regulatory examples will be presented as well as identification of areas for improvement.

The views expressed in this paper are solely those of the authors and the content of the paper does not represent the views or position of the European Chemicals Agency