

The Necessity of Uncertainty:
Quantifying Uncertainty for Regulatory Application of New Approach Methodologies
Wednesday, March 13th at 11:00 am to 12:20 pm
Baltimore Convention Center, room 314

References and resources

Hoffman, F and J Hammond. (1994) Propagation of Uncertainty in Risk Assessments: The Need to Distinguish Between Uncertainty Due to Lack of Knowledge and Uncertainty Due to Variability. <https://doi.org/10.1111/j.1539-6924.1994.tb00281.x>

Paparella, M., Colacci, A. and Jacobs, M. (2017). Uncertainties of testing methods: What do we (want to) know about carcinogenicity?. *ALTEX – Alternatives to animal experimentation*. 34, 2 235-252. DOI:<https://doi.org/10.14573/altex.1608281>.

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Patlewicz G, et al. (2015) Proposing a scientific confidence framework to help support the application of adverse outcome pathways for regulatory purposes. *Regulatory Toxicology and Pharmacology* 71:465-477. <https://doi.org/10.1016/j.vrtph.2015.02.011>

US Environmental Protection Agency's General guidance information on assessing uncertainty and variability in exposure and risk assessments
<https://www.epa.gov/expobox/uncertainty-and-variability#res>

US Food and Drug Administration' 2018 Draft Guidance: Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions

(Worth's presentation references)

ECHA (European Chemicals Agency) (2012). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.19: Uncertainty Analysis.
https://echa.europa.eu/documents/10162/13632/information_requirements_r19_en.pdf

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<https://doi.org/10.2903/j.efsa.2017.4971>

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<https://doi.org/10.2903/j.efsa.2019.5520>

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[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env/jm/mono\(2007\)2](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env/jm/mono(2007)2)

OECD (Organisation for Economic Cooperation and Development) (2005). Guidance Document on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment. *OECD Series on Testing and Assessment* No. 34, ENV/JM/MONO(2005)14.
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https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_014.pdf

WHO (World Health Organisation) ICPS (International Programme on Chemical Safety) (2017). Harmonization Project Document 11. Guidance Document on Evaluating and Expressing Uncertainty in Hazard Characterisation. Second edition.
<http://www.inchem.org/documents/harmproj/harmproj/harmproj11.pdf>