The Final EUTOXRISK Symposium 32

Communication strategy to harmonize research and regulatory needs

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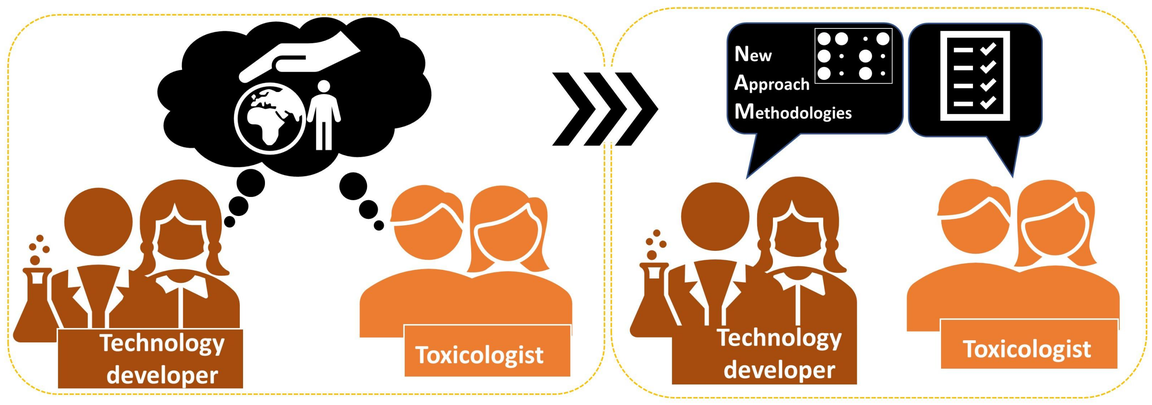
Different dialects, same mission

The interdisciplinary science of toxicology applied to real-life public health problems requires the active involvement of different actors. These actors, such as technology developers and regulatory toxicologists, do not always share the same communicational background.
Nevertheless, close interaction among researchers and regulators can significantly improve the implementation of new technologies into regulatory needs, thereby enhancing the societal impact of the project.



Communication is a "two-way process" of reaching mutual understanding, in which actors not only exchange (encode-decode) information but also create and share meaning.

To be uniquely encoded/decoded information MUST include

„context & purpose"
„glossary & definitions"
„sub-questions & exemplifications"

Case studies as a communication tool

Case studies are excellent to get familiar with and to demonstrate the scientific validity of NAMs. The project's Regulatory Advisory Board (RAB) has been involved in the refinement of the case studies to fit a clear regulatory purpose. The interaction with RAB and the OECD via the submission of case studies has been critical to fully appreciate the specificity and limitations of NAMs.
Learnings for scientists included: making use of very explicit regulatory questions; selecting NAMs based on their being fit for purpose; developing a communal language and establishing direct and open communication.

Identified regulatory needs	Solutions adopted by EU-ToxRisk
▪ Fit-for-purpose in current legislative frameworks. Clear identification of applicability domain.	▪ Refinement of regulatory question into the case studies. Dialogue platform with policymakers and regulators (see posters #31 and #36)
▪ Description of single test methods in a common language/ontology	▪ Development of test system description templates (see ToxTemp poster #33)
▪ Logical and transparent reporting of the testing strategy and its components	▪ Development of case study reporting template to describe the testing strategy (see Case Study Approach poster #12)

This cooperation has resulted in an improved understanding of requirements and pitfalls of NAM-supported risk assessment, from a scientific, academic, and regulatory perspective.
Conversely, participating regulators were required to discuss risk assessment against the backdrop of state-of-the-art scientific insights and technologies, thus being forced to actively reflect on existing paradigms as well as their potential roles concerning the integration of NAMs into legal frameworks.

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www.eu-toxrisk.eu/