



NAMs in chemical risk assessment: a new game requires new rules

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The opinions expressed in this presentation are solely those of the presenter and not necessarily those of the RIVM (National Institute for Public Health and the Environment).



NAMs: science and technology perspective

- Major advances have been made in the past decades
- Resulting in fancy toolboxes, consisting of a large variety of NAMs
- ...and they keep growing and improving





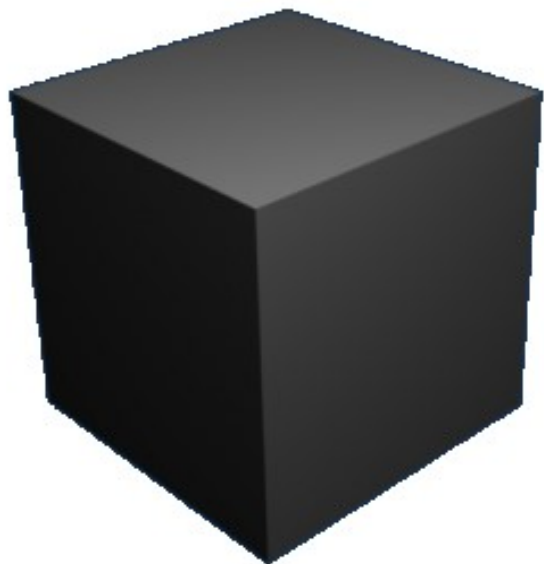
NAMs: regulatory perspective - 1

- For regulatory application of NAMs, there is in general lack of sufficient insight into:
 - performance
 - human relevance
 - applicability domain
 - associated uncertainties
- These insights are needed for single use and for use in combination with other NAMs, *i.e.* in integrated approaches



NAMs: regulatory perspective - 2

- NAMs are increasingly complex: risk of insufficient understanding



Current approaches for toxicity testing

NAMs



NAMs in regulatory risk assessment

Communication between regulators and industry needs to be strengthened:

- What are the possibilities and limitations of (combinations of) NAMs used by industry?

and

- What NAMs are considered acceptable by regulators? What criteria need to be met, what are credibility factors?



How to proceed?



Start a new game with new rules!





NAMs: the way forward



- System for regulatory use of NAMs
 - consensus on validation
 - consistent and transparent description of NAMs, covering both possibilities and limitations
 - context-of-use: prioritization, classification, screening or risk assessment
 - consensus on criteria/credibility factors
- Dedicated research, incl. case studies, are valuable contributions to demonstrate how/when NAMs are fit-for-purpose
- Aim for a transition period, where NAMs are used in parallel to current approaches → allows for capacity building and stakeholders to become familiar with NAMs

