

US Strategic Roadmap Goal: Encourage the Use and Adoption of New Methods and Approaches by Federal Agencies and Regulated Industry

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A lack of clear guidance on the status of regulatory acceptance is often cited by industry stakeholders as a significant factor impeding the use of new methods and approaches. To facilitate use by industry, agencies should provide clear guidance on the use and acceptance of data from new approach methodologies (NAMs). Additionally, frequent and transparent communication with international partners will ensure that development and evaluation of NAMs are harmonized, where feasible, to account for international regulatory requirements. Such coordination is essential because in a global economy, efforts by individual countries to develop NAMs will have little impact without international adoption of the new methods, as companies will always test according to the requirements of the most conservative country.

The successful implementation of NAMs will also depend on agencies and stakeholders working together to identify factors and develop solutions that enable the widespread use of NAMs. For example, training programs on the use of a new method should be established for personnel who conduct or review toxicology studies. Accordingly, federal agencies must take an active role in processes required for the successful adoption and use of NAMs, both within the federal government and internationally.

With all of these points in mind:

- Agencies should adopt clear language regarding the acceptance of NAMs.
- Agencies should collaborate with international partners to facilitate global harmonization and regulatory acceptance.
- Agencies and stakeholders should work together to explore processes to incentivize and promote the use of NAMs.