New Approach Methodologies (NAMs) in Future Food Safety Risk Assessment

a Joint Workshop by World Health Organization (WHO) and Nanyang Technological University, Singapore (NTU Singapore)

Date:
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Location:
Royal Plaza on Scotts, Singapore, 25 Scotts Road, Orchard 228220, Singapore

Introduction:

Traditional methods for assessing chemical risks to human health are facing limitations, such as validity concerns and societal pressure to transition to animal-free methods. The future of chemical safety and risk assessment is evolving rapidly with the emergence of New Approach Methodologies (NAMs). NAMs are defined as methods and technologies aimed to be used to inform hazard and risk assessment while reducing or avoiding the use of animals. NAMs such as *in silico* computational models*, in vitro* assays, omics technologies, and Adverse Outcome Pathways (AOPs) can be used alone or in combination. These technologies offer more accurate, human-relevant insights into exposure of chemical and biological hazards, while reducing reliance on animal testing.

Despite the scientific advancements of NAMs, their regulatory integration remains slow. Barriers such as regulatory acceptance, lack of global harmonization, data gaps, and infrastructure limitations must be addressed. This workshop aims to foster a global dialogue to advance the adoption and practical implementation of NAMs in chemical safety, bridging gaps between scientific innovation and regulatory frameworks.

Workshop Objectives:

- **Bridge** the gaps between scientific innovation and regulatory frameworks
- **Foster** a global dialogue to advance the adoption and practical implementation of NAMs in chemical safety
- **Assess** NAMs' status and prospects for novel foods

Key Topics and Themes:

1. **The State of NAMs and Next-Generation Risk Assessment**:
   - Overview of NAMs, including *in vitro*, *in silico*, and mechanistic approaches.
   - Examples of NAM success stories and key challenges in different regions.
   - Next Generation Risk Assessment (NGRA) and its role in supporting risk assessments without animal testing.
2. **Global Regulatory and Technical Challenges**:
   - Regulatory hurdles preventing widespread NAMs adoption.
   - Harmonizing global frameworks and standards for NAM validation and use.
   - Legal, ethical, and cultural barriers in different regions and industries.
3. **Capacity Building for Low- and Middle-Income Countries**:
   - How NAMs can be integrated in LMICs, focusing on data gaps, technical tools, and infrastructure challenges.
   - Developing regional roadmaps for NAM implementation, considering local regulations and resources.
4. **Practical Implementation of NAMs**:
   - Case studies illustrating how NAMs are being successfully used in chemical risk assessments across the globe.
   - Hands-on training on tools and technologies required to utilize NAMs effectively.
5. **Future of NAMs: Recommendations and Next Steps**:
   - Panel discussions on the future direction of NAMs in regulatory science.
   - Development of global recommendations to guide NAMs integration and acceptance by regulatory bodies.
   - Strategic planning for future collaborations and partnerships to promote global NAM adoption.

Expected Outcomes

1. **Global Recommendations for NAM Implementation:**
   Clear guidelines and recommendations for global regulatory bodies on how to adopt NAMs in chemical safety assessments.
2. **Capacity Building Roadmap:**
   A roadmap for building technical and human resource capacity in LMICs to support the widespread use of NAMs.
3. **Collaborative Partnerships:**
   Establishment of partnerships between regulatory agencies, academic institutions, and industry stakeholders to facilitate the global adoption of NAMs.

Target Audience:

- Public health and food safety agencies
- Regulatory bodies
- Academic researchers and scientists focused on NAMs development.
- Industry professionals from sectors including pharmaceuticals, chemicals, and food safety.
- Representatives from low- and middle-income countries