



International Alliance for
Biological Standardization

**Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy**
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Korea's Strategy for NAMs Adoption: Harmonizing Regulatory Science and Innovation

This presentation outlines South Korea's comprehensive strategy for transitioning from traditional animal testing to New Approach Methodologies (NAMs), positioning the country as a leader in ethical and efficient regulatory science. This shift represents a fundamental paradigm change, moving toward human-centric, highly predictive models that enhance both scientific robustness and ethical standards in safety assessment.

The strategy is built upon three interconnected pillars:

1. **Legal and Policy Foundation:** Korea has demonstrated strong regulatory commitment by enforcing mandatory NAMs use in the cosmetics sector and is currently advancing the "Alternative Test Methods Promotion Act (Draft)" to establish a uniform legal framework across all regulatory sectors (biologics, chemicals).
2. **Innovation and Infrastructure:** To drive technological readiness, the government is prioritizing the development and standardization of next-generation NAMs, particularly Organoid/Organ-on-a-Chip technology and AI-based toxicity prediction. This research is facilitated through the K-Consortium Model, a robust public-private-academic partnership designed to rapidly translate research into industrial application and standardized protocols.
3. **Regulator-Driven Transformation:** A pioneering national initiative is underway to replace the high-concern Mouse LD50 assay for Botulinum Toxin potency testing with a validated Cell-Based Assay (CBA) by 2029, illustrating a commitment by the regulatory body (MFDS) to actively update core national standards. This transition is overseen by the Korean Center for the Validation of Alternative Methods (KoCVAM), which ensures scientific credibility and global alignment with OECD standards.

In conclusion, South Korea's integrated approach—combining legal mandate, R&D investment, and active regulatory transformation—aims to achieve global standards, foster public trust, and proactively lead the international harmonization of ethical and efficient regulatory science.

