

SOT Informational Session

The International Cooperation on Alternative Test Methods (ICATM): Translating Science to Provide Improved Public Health Safety Assessment Tools



William Stokes, DVM, DACLAM

- ICATM: Translating Science to Provide Improved Public Health Safety Assessment Tools



Marilyn Wind, PhD, Former Chair, ICCVAM, U.S. CPSC (ret)

- NICEATM and ICCVAM: Recent ICATM Contributions and Future Plans



Joachim Kreysa, ECVAM, JRC, Italy

- ECVAM: Recent Contributions to ICATM and REACH and Future Plans



Hajime Kajima, PhD, JaCVAM, NIHS, Japan

- JaCVAM: Recent ICATM Contributions and Future Plans



Mike Inskip, HECSB, Health Canada

- Health Canada's Role in ICATM

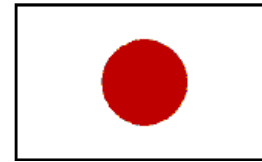


Soon Young Han, PhD, NIFDSA, KoCVAM, Korea

- KoCVAM: Recent Progress and Future Plans

Introduction and Overview

The International Cooperation on Alternative
Test Methods (ICATM):
Translating Science to Provide Improved Public
Health Safety Assessment Tools



William Stokes, DVM, DACLAM
RADM, U.S. Public Health Service
Director, NICEATM
Executive Director, ICCVAM

Informational Session
Society of Toxicology 50th Anniversary Annual Meeting
March 7, 2011 – Washington, DC

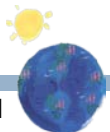
International Cooperation on Alternative Test Methods (ICATM)

■ Memorandum of Cooperation

- Original Signed: April 27, 2009
- Signing of 1st Modification: March 8, 2011, SOT Meeting

■ Signatories

- **Dr. Linda Birnbaum**,
Director, NIEHS and NTP, USA
- **Dr. Masahiro Nishijima**,
Director General, National Institute of Health Sciences, Japan
- **Dr. Elke Anklam**, Director, Institute of Consumer Protection and Health,
Joint Research Centre, European Commission
- **Dr. David Blakey**, Director, Health and Safety Bureau, Health Canada
- **Dr. Seung Hee Kim**, Director General, National Institute of Food and
Drug Safety Evaluation, Korea Food and Drug Administration



ICATM Organizations

ICATM is a **voluntary** international cooperation of national organizations: Canada, the European Union, Japan, South Korea, and the United States.



Health
Canada



NICEATM-
ICCVAM



ECVAM

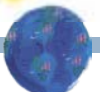


KoCVAM

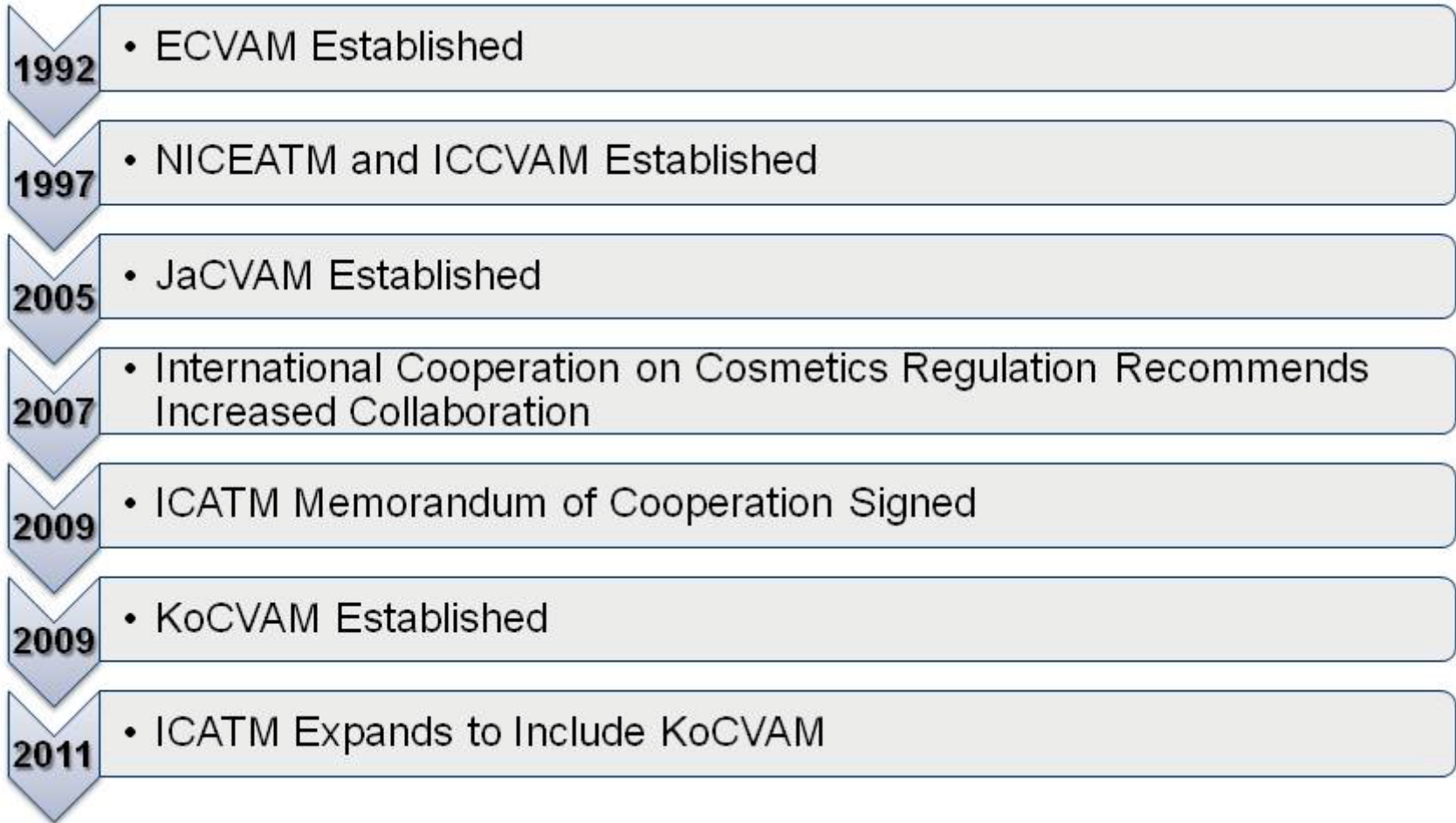


JaCVAM

ICCVAM
NICEATM

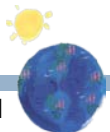


Evolution of National Validation Organizations and ICATM

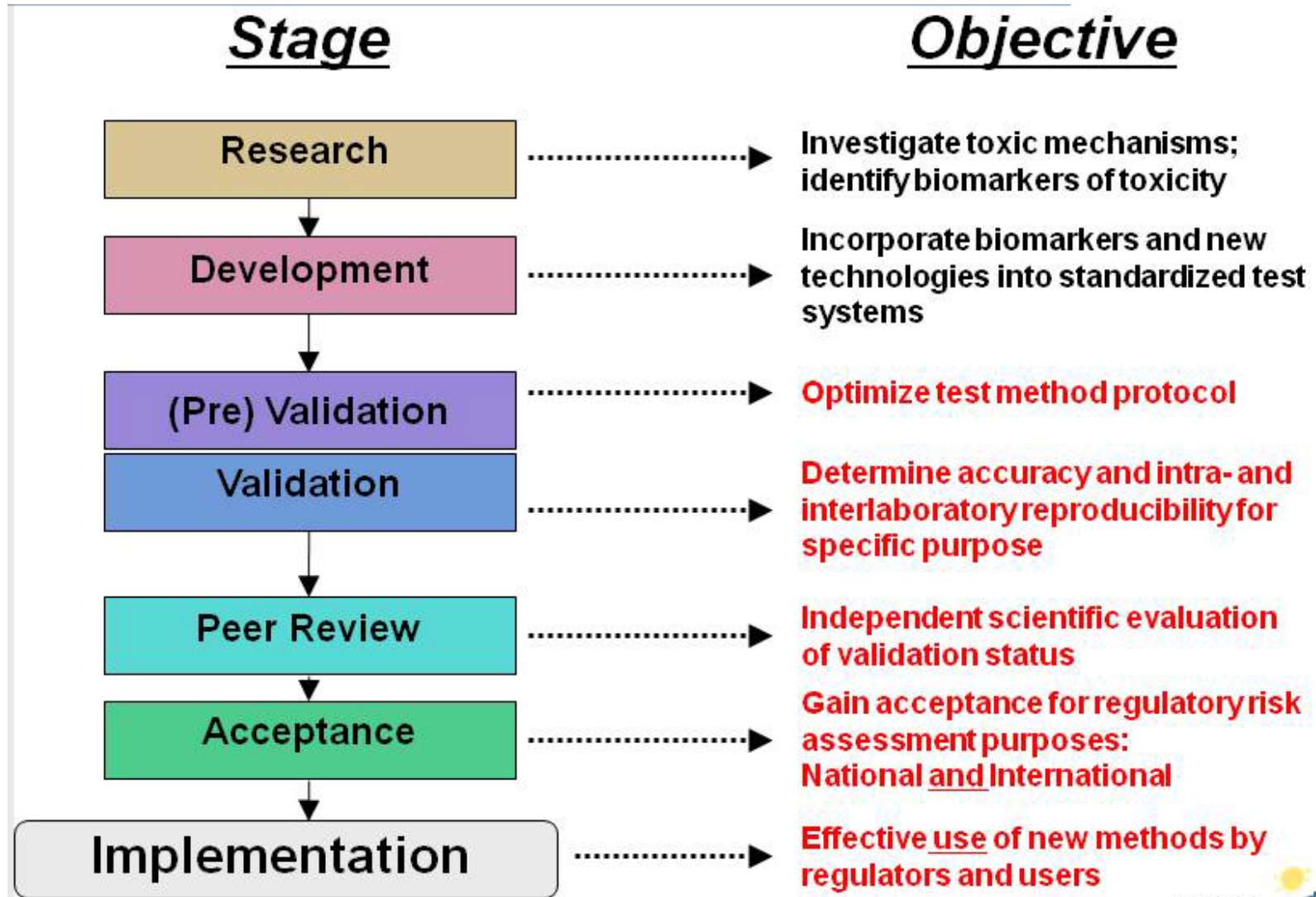


International Drivers for Establishment of National Validation Centers

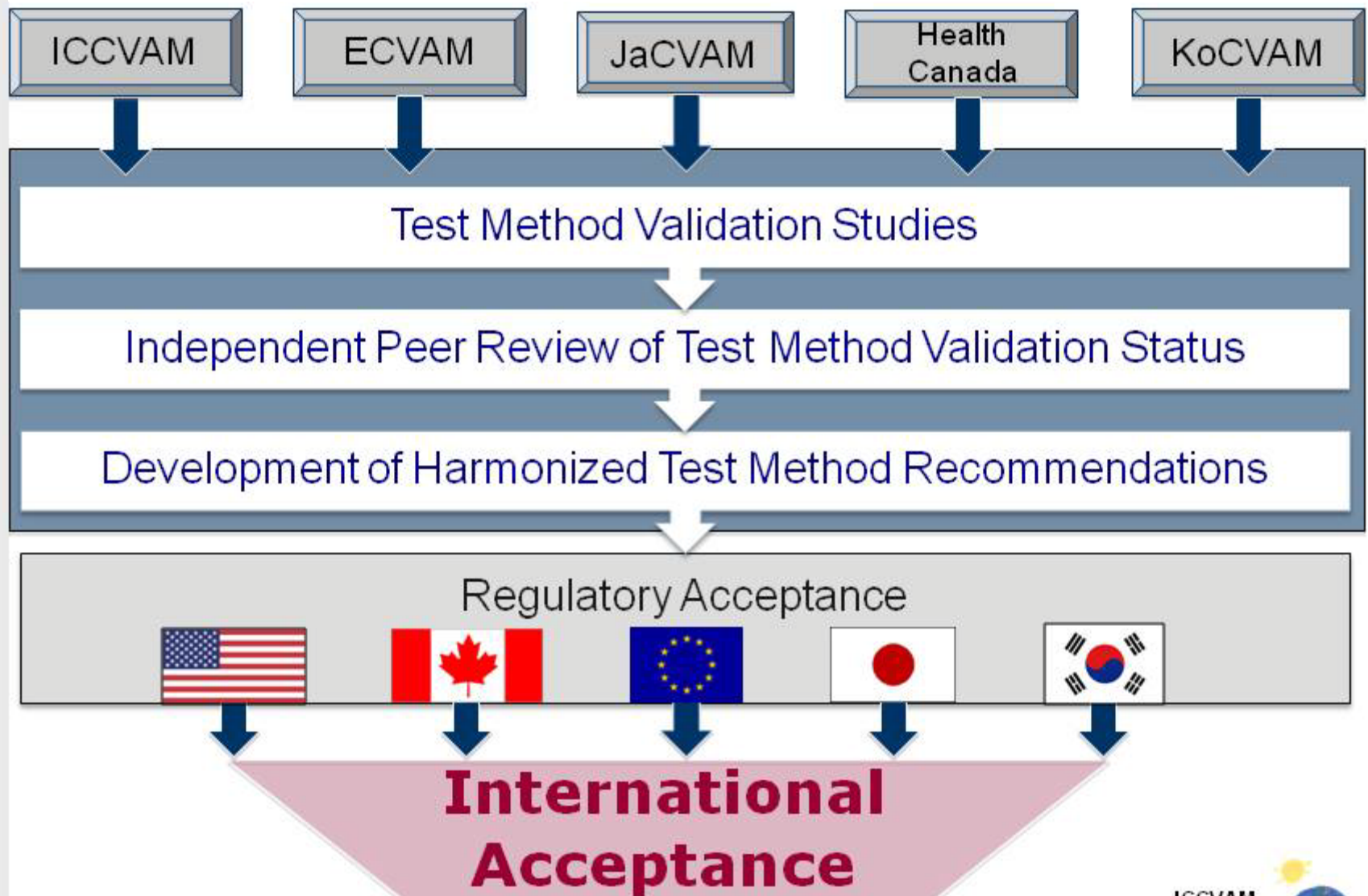
- Advances in science and technology: opportunity to develop improved test methods
- The need for a translational infrastructure to move science from the bench to approved regulatory safety tools
 - Recognition of the critical role of validation and scientific review and evaluation
 - Validation: determining the usefulness and limitations of a test method for a specific purpose within and across different labs (relevance and reliability)
- Emphasis on improved public health and **prevention** of diseases and injuries from chemicals and products
- Increased emphasis on animal welfare and the 3Rs



Translating New Science and Technology Into Regulatory Safety Assessment Methods and Approaches




ICATM Cooperation



ICATM Contributions: Adoption of International Test Guidelines 2009-2010

Allergic Contact Dermatitis (skin sensitization)

TG 429: Skin Sensitisation (LLNA)  Up to 40% decrease in animals used

TG 442A: Skin Sensitisation (LLNA: DA)
TG 442B: Skin Sensitisation (LLNA: BrdU-ELISA)  "Green" test methods (radioisotopes not required)

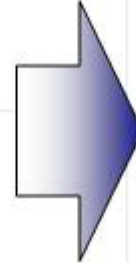
Skin Irritation

TG 439: *In Vitro* Skin Irritation  First *in vitro* test methods for this purpose

Genetic Toxicity

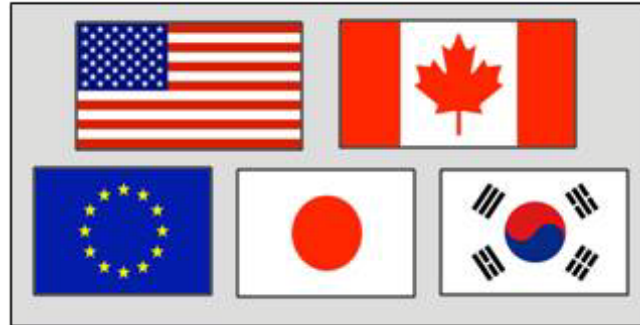
TG 487: In Vitro Mammalian Cell Micronucleus Test  Non -animal alternative for this endpoint

Ocular Toxicity

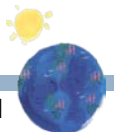
TG 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants
TG 438: Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants  Ocular corrosives and severe irritants can be identified without testing in animals



Summary: ICATM Purposes and Goal



- Promote consistent and enhanced cooperation, collaboration, and communication among national validation organizations
- Achieve greater efficiency and effectiveness
- Incorporate transparency and stakeholder involvement
- Speed international adoption of valid alternative methods
- Goal: Maintain or improve protection of people, animals, and/or the environment while reducing, refining, and replacing animals whenever scientifically feasible



Thank you for your attention.

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NICEATM – ICCVAM
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This presentation may not necessarily reflect the official position of any U.S. Agency.



*The USPHS Commissioned Corps:
Protecting, Promoting, and Advancing the Health and Safety of the Nation*

