

Session 23. Asia: A place ripe for the development of 21st century science

Promoting alternatives to animal testing methods through stakeholder collaboration

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Outline

- Statistics on the animal testing, alternatives in South Korea
- Different authorities, different rules
- Multi-stakeholder discussion
- Lessons from other agencies
- Necessity for new legislation - Act on the Promotion of Development, Dissemination and Use of Alternatives to Animal testing Methods

Lab Animal Statistics in South Korea



In 2020:

4,141,433 animals used for testing

Compared to 2019:

11.5% increase

22% increase for regulatory testing

Compared to 5 yrs ago:

43.8% increase

Different authorities, different rules

But nothing to promote & harmonise NAMs



COSMETICS



Ministry of Food and Drug Safety



INDUSTRIAL CHEMICALS



Ministry of Environment

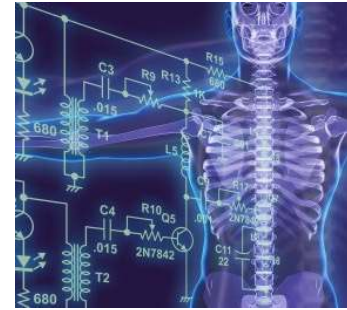


PESTICIDES



Rural Development Administration

Ministry of Industry



DISEASE



Ministry of Education

Ministry of Science and ICT



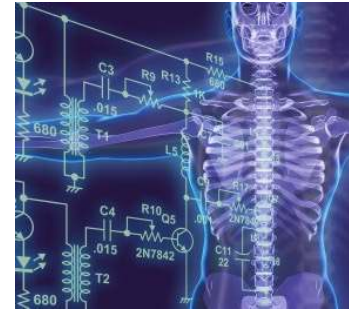
MEDICAL DEVICES



Ministry of Health and Welfare

Different authorities, different rules

But nothing to promote & harmonise NAMs



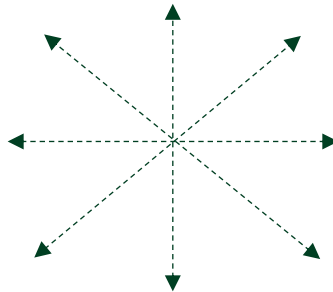
Ministry of Food and Drug Safety

Ministry of Education

Ministry of Environment

Ministry of Health and Welfare

Korea Center for the Validation of Alternative Methods



Rural Development Administration

Ministry of Industry

Ministry of Science and ICT

Different authorities, different rules

But nothing to promote & harmonise NAMs

Korean saying “Pouring water in a bucket with holes”



Different authorities, different rules



“... try to accept more alternative test methods but not enough... will work on collaboration with other authorities to expand alternative methods in Korea....”

Environment minister during 2016 government enquiry



“... will try to be more proactive in accepting alternative methods and global harmonization for test guidelines....”

Rural Development Administrator
during 2017 government enquiry

Multi-stakeholder discussion

Government

Private company

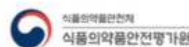
Universities

Hospital

NGO



<동물대체시험 개발·보급·이용을 위한 온라인 세미나>



새로운 독성평가 패러다임

통합시험평가접근법

(Integrated Approaches to Testing and Assessment, IATA)

국내 및 글로벌 활용 사례 소개

Different authorities, different rules

NAMs are becoming mainstream in other countries but not in Korea.

Communication barrier between industries and authorities

SMEs can't invest in developing NAMs.

No support for infrastructure while developing methods

We need detailed plans from government to support NAMs.

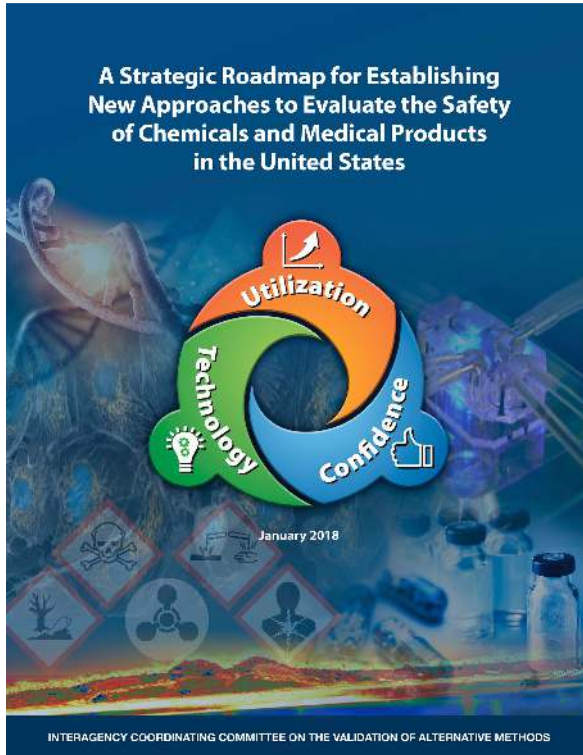
No platform for connection and sharing information

Our team worked hard to develop internationally validated method but it's not used in Korea.



Lessons from other agencies

Importance of stakeholder communication

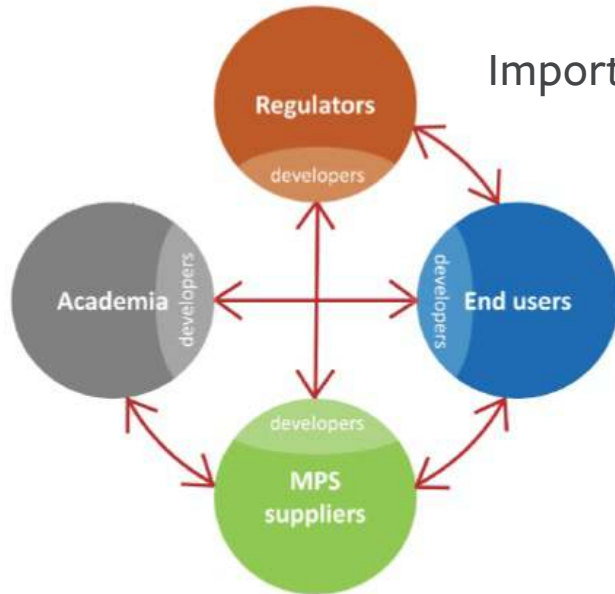


- (1) **Connect** end users with the developers of NAMs
- (2) **Foster** the use of efficient, flexible, and robust practices to establish confidence in new methods
- (3) Encourage the **adoption** and **use** of new methods and approaches by federal agencies and regulated industries

<https://dx.doi.org/10.22427/NTP-ICCVAM-ROADMAP2018>

Lessons from other agencies

Importance of stakeholder communication



“Smart sustainable communication balance between the four stakeholders is required to close the current communication gap on a global scale.”

Box 4: How to support MPS-based assay qualification activities

All stakeholders: To foster the further growth and establishment of centres for evaluation and validation of MPS-based methods in America, Europe and Asia under the supervision of regulators. Involve all stakeholders in co-funding of such centres and ensure coordination of the evaluation and validation programs of such centres to avoid redundancy across the globe.

End users

qualification

End users

various set

based assa

pharmaceu

“All stakeholders: To foster the further growth and establishment of centres for evaluation and validation of MPS-based methods in America, Europe and Asia under supervision of regulators.”

Box 5: Addressing the regulatory acceptance dilemma

End users and suppliers: To make internal feasibility studies on MPS-based tests with a given fit for purpose publicly available, wherever possible.

End users, suppliers and regulators: To generate use cases for MPS-based assays under the supervision of an end user.

Regulators: To produce a position paper on aspects of regulatory acceptance of biology-inspired MPS-based assays for drug testing under supervision of US FDA involving American, European and Asian regulatory agencies. This should guide sponsors to learn how the agencies deal with the data based on case examples.

Regulators: To establish a standardized annual meeting format to convene a group of regulators from America, Europe, Asia and other geographies in the drug, food, and biologics space

- o coordinating regulatory science,
- o tracking and analysing MPS-based data arrival at a regulatory level (e.g. IMPD, IND),
- o organizing the development of ICH guidelines for those MPS-based assays which make it to replace existing animal-based ICH guidelines.

Necessity for new legislation

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Act on the Promotion of Development, Dissemination and Use of Alternatives to Animal testing Methods (PAAM Act)

bill sponsored by National Assembly member In-soon Nam, under jurisdiction of Ministry of Food and Drug Safety

- 1 (Purpose)
- 2 (Definition)
- 3 (Responsibilities of the state)
- 4 (Relationship with other laws)
- 5 (Establishment, execution, tec. of master plans and implementation plans)
- 6 (Alternative to animal testing methods committee)
- 7 (Fact-finding survey)
- 8 (Promotion, etc. of R&D activities)
- 9 (Promotion of dissemination and use)

- 10 (Establishment and operation of information system)
- 11 (Establishment of the Korean Center for the Validation of Alternative Methods)
- 12 (Training of specialized personnel)
- 13 (Protection of intellectual property, etc.)
- 14 (Global collaboration)
- 15 (Tax reduction)
- 16 (Delegation of authority and test contract)
- 17 (Legal fiction of public official in application of penalty provisions)

Act on the Promotion of Development, Dissemination and Use of Alternative to Animal testing Methods

Article 1 (Purpose) The purpose of this Act is to designate necessary measures to promote the development, distribution and use of alternatives to animal testing methods, thereby encouraging development of life science and enhance public health welfare by harmonizing human welfare and animal dignity.

Article 2 (Definition)

- (1) 'Alternatives to animal testing methods' mean to testing methods that do not use animals, resulting in reducing animal use,
- (2) 'Relevant central authorities' refer to Ministry of Science and ICT, Ministry of Trade and Industry, Ministry of Health and Welfare, Ministry of Education, Ministry of SMEs and Ministry of Agriculture, Food and Rural Affairs.

Act on the Promotion of Development, Dissemination and Use of Alternative to Animal testing Methods

Article 5 (Establishment, Execution, etc. of Master Plans and Implementation Plans)

(1) Minister of Food and Drug Safety shall discuss with the heads of relevant central agencies to establish and implement a master plan to promote development, distribution and use of alternative methods every five years

(2) A Master Plan shall include following information:

1. Basic objectives and directions on the development, distribution and use of alternatives to animal testing methods;
2. Analysis of domestic and international trends in development, distribution and use of alternatives to animal testing methods
3. Support and outcome management for research and development of alternatives to animal testing methods;
4. Establishment and management of the information system for alternatives to animal testing methods;
5. Methods of systematically training and providing support for research and development of alternatives to animal testing methods;
6. Support for private sector technology development for alternatives to animal testing methods
7. Promotion of global cooperation in conducting research on alternatives to animal testing methods
8. Other matters necessary for the development, distribution and use of alternatives to animal testing methods.

Act on the Promotion of Development, Dissemination and Use of Alternative to Animal testing Methods

Article 9 (Promotion of dissemination and use of alternatives to animal testing methods)

(1) The Minister and heads of relevant central authorities shall establish and implement following matters to promote dissemination and use of alternatives to animal testing methods

1. Management and trade of information regarding alternative methods
2. Collaboration for personnel, skills, infrastructure, etc. between industry, academia, research institute and other relevant facilities and organisations
3. Other matters necessary to promote the distribution and use of alternative methods

(2) Minister and heads of relevant central authorities can provide necessary support pursuant to the presidential decree for industry, academia or research institute, etc. that is participating in the project pursuant to ①.

(3) Matters necessary to establish and implement policy pursuant to ① are as prescribed by the Presidential Decree

Act on the Promotion of Development, Dissemination and Use of Alternative to Animal testing Methods

Article 11 (Establishment of the Korean Center for the Validation of Alternative Methods)

(1) [Korea Center of the Validation of Alternative Methods](#) (hereafter ‘the center’) is established under the Minister of Food and Drug Safety for effective operation of policies to promote the development, distribution and use of alternative methods

(2) The center conducts following tasks;

1. Research and development of alternative methods
2. Survey and research of policy or system to promote the development, distribution and use of alternative methods
3. Validation and assessment to acknowledge alternative methods
4. Proposal of international guidelines for alternative methods developed in Korea
5. R&D information management, distribution and education for alternative methods
6. Establish collaborative structure and collaborative research with relevant international and national facilities
7. Other matters necessary to promote the development, distribution and use of alternative methods

(3) Other matters regarding management and operation for the center is prescribed by the Presidential Decree

Act on the Promotion of Development, Dissemination and Use of Alternative to Animal testing Methods

Article 13 ([Protection of Intellectual Property, etc.](#)) The Minister shall establish and implement necessary policies for protecting copyrights and other intellectual property rights (hereinafter in this Article referred to as “the IPRs”) in connection with promotion of the development, distribution and use of alternative methods.

Article 14 ([Global Collaboration](#)) The Minister shall establish policies for global collaboration including the exchange of information, joint survey and research, and the exchange of technology, to promote global collaboration related to alternative methods.

Article 15 ([Tax Reduction](#)) The State or local governments may give tax reductions to promote development, distribution and use of alternative methods as prescribed by the Restriction of Special Taxation Act and the Restriction of Special Local Taxation Act.

Promoting alternatives to animal testing methods through stakeholder collaboration





**HUMANE SOCIETY
INTERNATIONAL**

KOREA

Thank you.

bseo@hsi.org