

KoCVAM update

(July 2011 ~ August 2012)

SACATM Meeting
September 6, 2012

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Research Activities on Alternative Test Methods

Performance Standard Based Validation Study

- Skin sensitization test
 - Object
 - Assess the reliability and transferability using coded chemicals according to the performance standard (OECD TG429)
 - Test method
 - Non-radioactive local lymph node assay using flow cytometry
 - Status
 - 3 labs (2 CRO, 1 Cosmetic industry) participate in the validation study
 - VMT meeting to approve SOP
 - Distribute 3 coded substance according to the guideline

Performance Standard Based Validation Study

- Skin irritation test
 - Object
 - Assess the reliability and transferability using coded chemicals according to the performance standard (OECD TG439)
 - Test method
 - *In vitro* skin irritation test using reconstructed human epidermis model developed in Korea
 - Status
 - Developing study plan and SOP
 - 3 labs (2 CROs, 1 Cosmetic industry) participate in the validation study
 - Organize Validation Management Team

Participation in International Validation Study

- A Korean CRO (Biotoxtech) participates in JaCVAM-led international validation study
- Test method
 - SIRC cytotoxicity test for eye irritation
- Status
 - Phase I study completed (2011.12~2012.4)
: 4 coded test substances
 - Phase II study on-going (2012.5 ~)
: 20 coded test substances
 - Participation in face to face meetings

Participation in International Collaborative Study

- A Korean CRO (Korea Institute of Toxicology) participates in NC3Rs-led international collaboration study to develop “fixed concentration procedure for acute inhalation toxicity” guideline (draft OECD TG433)
- Status
 - Recommend a Korean CRO (2011.11.)
 - Participation in teleconference (2012.2.)
 - Collect study data on acute inhalation toxicity (~2012.12.)

Participation in International Collaborative Study: Biological Test

- 4 labs including National Center for Lot Release of KFDA participate in EDQM-led international collaborative study for developing *in vitro* test method for acellular pertussis vaccine
- Test method
 - *In vitro* method for specific toxicity of pertussis vaccine using ELISA
- Status
 - Receive test substances
 - Results of collaborative study will be presented in upcoming workshop

International Collaboration



Participation in International Workshop Organizing Committee

- NICEATM/ICCVAM-led international workshop on alternatives to the murine histamine sensitization test (HITS) for acellular pertussis vaccine
 - Nominate a Korean expert as organizing committee's member (2012.5.)
(Dr. Ho Kyung Oh, NIFDS/KFDA)
 - Participation in teleconferences (2012.6~)

Participation in Validation Management Team

- NICEATM/ICCVAM-led validation study
 - MCF-7 proliferation assay
 - Participation in face-to-face meeting (2011.8.)
 - Provide comments on draft of a validation study report (2012.8.)

Participation in Validation Management Team

- JaCVAM-led validation study
 - *In vitro* Comet assay (2010.3.~)
 - ROS assay for phototoxicity test (2011.6.~)
 - Participation in teleconference (2011.7.)
 - *In vitro* skin sensitization test using IL-8 reporter gene assay (2011.8.~)
 - Participation in face to face meeting (2012.2.)

Participation in Peer Review Panel

- ESAC peer review panel
 - KeratinoSens assay for skin sensitization test
 - Nominate a Korean expert as ESAC peer review panel (2011.4.)
(Prof. Yong Heo, Catholic University of Deagu)
 - Participation in WGs at ESAC (2011.10.~)
 - Participation in face-to-face meetings (2011.10.~)

Other Activities



Adopted Test Guidelines of ATM for Cosmetics

- Korean guideline
 - Bovine Corneal Opacity and Permeability
(based on OECD TG438)
 - Status
 - Accepted as domestic guideline for ocular toxicity
of cosmetic ingredients (2011.6.30.)

KFDA Acceptance for Cosmetics

Method	International Acceptance	National Acceptance
<i>In vitro</i> 3T3 NRU phototoxicity test	OECD TG 432 (2004)	2007
Skin sensitization: Local Lymph Node Assay	OECD TG 429 (2007)	2007
Acute Oral Toxicity: Fixed Dose Procedure	OECD TG 420 (2002)	2008
Acute Oral Toxicity: Acute Toxic Class Method	OECD TG 423 (2002)	2008
<i>In Vitro</i> Skin Corrosion: Transcutaneous Electrical Resistance Test	OECD TG 430 (2004)	2008
<i>In Vitro</i> Skin Corrosion: Human Skin Model Test	OECD TG 431 (2004)	2008
<i>In Vitro</i> Membrane Barrier Test Method for Skin Corrosion	OECD TG 435 (2006)	2008
Skin Absorption: <i>In Vitro</i> Method	OECD TG 428 (2004)	2009
Bovine Corneal Opacity and Permeability assay	OECD TG 437 (2009)	2011

Adopted Test Guidelines of ATM in Other Agencies

- National Institute of Environmental Research (Ministry of Environment) (2006)
 - Acute oral toxicity: fixed dose procedure (OECD TG420)
 - Acute oral toxicity: acute toxic class method (OECD TG423)
 - Acute oral toxicity: up-and-down procedure (OECD TG425)
- National Academy of Agricultural Science (Rural Development Administration) (2012)
 - Acute oral toxicity: fixed dose procedure (OECD TG420)
 - Acute oral toxicity: acute toxic class method (OECD TG423)
 - Skin sensitization: local lymph node assay (OECD TG429)
 - Skin sensitization: local lymph node assay:DA (OECD TG442A)
 - Skin sensitization: local lymph node assay:BrdU-ELISA (OECD TG442B)

4th KoCVAM Workshop for Experimental Training

- When : May 15th, 2012
- Where : National Institute of Food and Drug Safety Evaluation/KFDA
- Program
 - Basic principle of flow cytometry
 - Operation of flow cytometry
 - Analysis of BrdU-labeled samples



3rd KoCVAM-KSAAE Joint International Symposium

- When: July 8th, 2011
- Subject : Current status of alternative tests in Asia
- Program
 - Current and future of correlation with Japan and Korea on alternative to animal experiments (JSAAE, Dr. Yoshihiro Ohmiya)
 - New multicolor reporter gene assay for toxicity test (JaCVAM, Dr. Hajime Kojima)
 - China's alternative test methods research in cosmetics: Current situation and prospect (Guangdong CDC, Dr. Xiong Xikkun)

4th KoCVAM-KSAAE Joint International Symposium

- When: August 31th, 2012
- Where: Biotoxtech
- Program
 - International effects leading to the development of a test guideline for the Pig-A assay (NCTR/FDA, Dr. Robert Heflich)
 - Current situation of Japanese alternative study (Osaka University, Dr. Kurosawa)
 - *In vitro* alkaline comet assay (Dongguk University, Dr. Young Ruk Seo)
 - Development of fixed concentration procedure and purpose of the clinical signs recording project (KIT, Dr. Kyuhong Lee)

1st Customized Service on Alternative Test Methods

Object

: To broaden the use of alternative test methods in Korea

- When : May 1st, 2012
- Where : Korea National Institute of Health/Korea CDC
- Program
 - KoCVAM establishment and activities
 - Global landscape of alternatives
 - Discussion of future collaboration



2nd Customized Service on Alternative Test Methods

- When : July, 27th 2012
- Where : Korea Testing and Research Institute (KTR)
- Program
 - Introduction on alternative tests
 - Current status of alternative tests
 - Introduction on *in vitro* skin irritation using REH (OECD TG 439)
 - Introduction on LLNA:BrdU-ELISA (OECD TG 442B)



Future Activities



Domestic Guidelines

- Skin sensitization: LLNA:DA (OECD TG 442A)
- Skin sensitization: LLNA:BrdU-ELISA (OECD TG 442B)

2013 International Congress of Toxicology



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June 30 - July 4, 2013 Coex, Seoul, Korea

Translational Toxicology:
From Basic Science to Clinical and Environmental Outcomes



The Korean Society
of Toxicology



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KEY DEADLINES

- **Extended deadline for Session Proposal**
‣ December 31, 2011
- **Deadline for Abstract Submission**
‣ January 31, 2013
- **Deadline for Early Registration**
‣ January 31, 2013
- **Deadline for Exhibition Booth Application**
‣ January 31, 2013

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Scientific Program of 2013 ICT

- Workshop
 - Title: Alternative test methods and international regulatory perspectives
 - Program
 - KoCVAM; Contributions to the implementation of alternative test methods in Korea and future plan
 - JaCVAM; Contributions to the implementation of alternative test methods in Japan and future plan
 - NICEATM/ICCVAM; Contributions to the implementation of alternative test methods in USA and future plan
 - EURL-ECVAM; Contributions to the implementation of alternative test methods in Europe and future plan
 - Health Canada; Contributions to the implementation of alternative test methods in Canada and future plan
 - Current status of development on alternative methods for screening skin sensitizer
 - Current status of animal alternatives in cosmetic industry: participation and perspectives

2013 International Congress of Toxicology

- Key deadlines
 - Deadline for abstract submission
 - January 31, 2013
 - Deadline for early registration
 - January 31, 2013
- More information can be found on the 2013 ICT web site
: www.ict2013seoul.org



Thank you for your attention