EPAA & INTERNATIONAL COOPERATION ON 3Rs

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Institute for In Vitro Sciences

Founded as a non-profit laboratory in 1997 to use and promote non-animal methods for toxicology

– We are supported by revenues from the in vitro testing services we perform, and from contributions (mostly corporate and NGOs).
– We interact internationally with governments, regulatory groups and NGO’s involved with non-animal methods
– We teach the methods

Being non-profit allows us to be a “neutral” party when working with regulatory agencies and industry, or interacting with animal welfare organizations.
International Programs

Acceptance and use of alternative methods is not just a European problem or a US problem.

Therefore IIVS has developed an International Outreach Program (IOP):

- supported by companies, associations and NGO’s.
- and containing an International Council for Advancing Regulatory Acceptance of Alternatives (ICARAA) – an industry-specific activity supported by annual memberships.

Hands-on trainings on OECD Test Guideline methods have been held in Brazil and China, and at IIVS for scientists from over a dozen countries.
Goal: Global Acceptance
For Non-Animal Methods

…but it’s not always that easy!
Country-specific barriers exist.
Goal: Global Acceptance For Non-Animal Methods

Requirements

• Common Methods, e.g. OECD Test Guidelines
• Common Understanding of Application
• Appropriate Infrastructure
• Desire to Harmonize
Proper National Infrastructure Is Mandatory

This Includes:

Trained Laboratories
Trained Industry Toxicologists
Trained Reviewers

Many Countries Lack One or More of These

All are objectives of EPAA and IIVS
MOU Statements

The two organisations consequently agree to:

• Combine resources and collaborate to promote international awareness and education in alternatives methods.

• Align actions related to their common goals and objectives informed by the needs within key geographies.

• Engage in science-based advocacy to build the knowledge base for alternatives
Our overall approach is to assist scientists and regulators in each country to learn and understand non-animal methods, not to prescribe when or how the methods are incorporated into their regulatory strategy.
IIVS educational/training activities (International Outreach Program) now financially supported by EPAA, ICARAA, and numerous NGOs.
Activities In China
Chinese Translation Of Abridged 3Rs

Abridged version more amenable to translation

3000 copies to be distributed free to Chinese universities and libraries. Contains EPAA logo and acknowledgement

Additional copies available to EPAA for distribution
ABSTRACT

Developing and utilizing toxicity assays that are more predictive of adverse events while at the same time reduce or eliminate the use of animals has become the goal of more and more cell culture, systems biology, toxicity pathway analysis, reconstructed human tissue constructs, etc. However, just the existence of a new set of tools will not by itself change the way toxicology is conducted. It will take communication and commitment from scientists in academia, industry, and the regulatory community – as well as political cooperation from governments – to transform the current animal-based regulatory paradigms to a 21st century approach involving mechanistic understanding of how biology is affected. An excellent example of how such cooperation can occur is the European Partnership for Alternative Approaches to Animal Testing (EPAA). The EPAA was formed to facilitate change in regulatory testing, and is a voluntary collaboration between the European Commission, European trade associations, and companies from seven industry sectors. The parties are committed to passing knowledge and resources to accelerate the development, validation and acceptance of alternative approaches to further the reduction, replacement and refinement (3Rs) of animals in animal testing.

POTENTIAL AND BENEFITS

Collaboration between different industry sectors and Commission involvement and leadership, combined with an efficient governance structure, enables:

- Holistic and innovative approach to safety testing, using the best available science and expertise
- Inter-sectoral industry/regulators dialogue
- Creating better understanding of testing requirements, developments and implementation of 3Rs
- Filling in research gaps in the field of 3Rs in safety testing by facilitating multi-stakeholder projects
- Rationalization of implementation of regulatory testing requirements
- Streamlining the process for the acceptance of alternatives

INTRODUCTION

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is a joint initiative from the European Commission, European trade associations from seven industry sectors and individual companies. It was launched in November 2005 with the purpose to promote the development and implementation of new 3Rs methods (replace, reduce, refine) and modern testing approaches. The Partnership activities cover:

- Mapping and dissemination of information about in-house methods and research programs
- Support to development of new alternative approaches and testing strategies
- Sowing better understanding and regulatory acceptance of 3Rs
- Dialogue with regulators on 3Rs and testing requirement

2012 ACTIVITIES

- Initiating new projects in the areas of advancing 3Rs in Regulatory Toxicology and harmonization of 3Rs in biology
- Launching various initiatives addressing the international aspects of alternative approaches to testing
- Organizing of meetings with the USFDA
- Sponsoring international conferences promoting 3Rs
- Creating better understanding of testing requirements, developments and implementation of 3Rs
- Filling in research gaps in the field of 3Rs in safety testing by facilitating multi-stakeholder projects
- Rationalization of implementation of regulatory testing requirements
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INTERNATIONAL ACTIVITY FOCUS

In an effort to ensure stronger international cooperation on advancing non-animal testing methods, the European Partnership for Alternative Approaches to Animal Testing (EPAA) and the Institute for In Vitro Sciences (IVS) have agreed to establish a strategic partnership dedicated to the international dissemination of alternative (in vitro) techniques for safety evaluation. The two organisations share a commitment to the development and promotion of the use of alternatives and believe that through cooperation they can better advance the awareness, availability and acceptance of alternative techniques to evaluate product safety.

EPA will provide financial sponsorship over the next two years to IVS to support training activities in key regions, including Brazil, China and Russia. Dr. Rodger Curren, President of IVS, stated that ‘‘EPA’s efforts to promote international cooperation on the 3Rs will be greatly complemented by our joint activities and solid international network.’’

CURRENT CHINA ACTIVITIES BY EPA/IVS

- Attending 2013 China SOT. IVS staff representing EPA will participate in and at scientific discussions.
- Financing part of translation and publication of a chapter written by Michael Balls of the Principles of Humane Experimental Technique (by B. Russell and R. Burch). Publication in association with Dr. Shujun Chung of Guangdong CIQ. Copies to be distributed free to China Universities.
- Encouraging lectures and training on the use of the Revised Corell Quality and Repeatability (BCOR) assay for new irritation.
- Attendance at IIVS meeting in Korea at request of Chinese delegation to introduce EPA activities.

ADDITIONAL INFORMATION

For additional information on the EPAA, its partners, and its activities, please scan the QR code below.
Attendance at ICT XII in Korea

IIVS attended representing EPAA

Interactions with Chinese toxicologist contingent

Introduction to history of KoCVAM formation, and process of acceptance of alternative methods in Korea
Additional Activities

• Technical and regulatory discussions with Chinese regulators and industry/academic scientists

• Promotion and training in BCOP assay for eye irritation

• Creation of training/instructional videos in multiple languages

• Planning for trainings in Russia and Brazil still in discussion
Laboratory Training Requires Close Cooperation With Host Country Staff
Example of Equipment Needed for Training
Training on BCOP assay in China
Training of Russian Regulators at IIVS

THANK YOU EPAA FOR YOUR SUPPORT OF IIVS INTERNATIONAL EDUCATION AND TRAINING PROGRAMS.